Newborn Screening Quality Assurance Program

2005 ANNUAL SUMMARY REPORT

Volume 23 January 2006

INTRODUCTION

The Newborn Screening Quality Assurance Program (NSQAP) is designed to help screening laboratories achieve excellent technical proficiency and maintain confidence in their performance while processing large volumes of specimens daily. We continually strive to produce certified dried-blood spot (DBS) materials for reference and quality control (QC) analysis, to improve the quality and scope of our services, and to provide immediate consultative assistance. Through our interactive efforts with the program's participants, we aspire to meet their growing and changing needs. We always welcome comments and suggestions on how we may better serve the newborn screening laboratories.

A major public health responsibility, newborn screening for detection of treatable, inherited metabolic diseases is a system consisting of six parts: education, screening, follow-up, diagnosis, management, and evaluation. Effective screening of newborns using DBS specimens collected at birth, combined with follow-up diagnostic studies and treatment, helps prevent mental retardation and premature death. These blood specimens are collected routinely from more than 98% of all newborns in the United States. State public health laboratories or their associated laboratories routinely screen DBS specimens for inborn errors of metabolism and other disorders that require intervention. For more than 27 years, the Centers for Disease Control and Prevention (CDC), with its cosponsor, the Association of Public Health Laboratories (APHL), has conducted research on materials development and assisted laboratories with quality assurance (QA) for these DBS screening tests. The QA services primarily support newborn screening tests performed by state laboratories; however, we also accept other laboratories and international participants into the QA program. All laboratories in the United States that test DBS specimens participate voluntarily in NSQAP. The program provides QA services for congenital hypothyroidism, phenylketonuria, galactosemia, congenital adrenal hyperplasia, maple syrup urine disease, homocystinuria, tyrosinemia, citrullinemia, biotinidase deficiency, galactose-1-phosphate uridyltransferase (GALT) deficiency, cystic fibrosis (CF), and hemoglobinopathies. QA services are also provided for urea cycle disorders, fatty acid oxidation disorders, and organic acid metabolic disorders.

The QA program consists of two DBS distribution components: QC materials for periodic use and quarterly proficiency testing (PT). The QC program enables laboratories to achieve high levels of technical proficiency and continuity that transcend changes in commercial assay reagents while maintaining the requisite high-volume specimen throughput. The QC materials, which are intended to supplement the participants' method- or kit-control materials, allow participants to monitor the long-term stability of their assays. The PT program provides laboratories with quarterly panels of blind-coded DBS specimens and gives each laboratory an independent external assessment of its performance. DBS materials for QC and PT are certified for homogeneity, accuracy, stability, and suitability for all kits manufactured by different commercial sources.

Over the last ten years, NSQAP has grown substantially, both in the number of participants and in the scope of global participation (Figure 1). In 2005, 368 newborn screening laboratories in 53 countries (at least one laboratory per country) were active program participants (Figure 2); of these, 308 participated in the PT component (Figure 4) and 295 in the QC part (Figure 5). One hundred twenty-four laboratories reported PT data using tandem mass spectrometry (MS/MS). Of these, 41 were domestic laboratories (Figure 3). MS/MS has made a major impact on the data reported to NSQAP (Figure 8).

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Disease Control and Prevention (CDC)
and the
Association of Public Health Laboratories

NSQAP
Contents

Program Information Web site:
http://www.cdc.gov/labstandards/nsqap.htm

Data-reporting Web site:
http://www2.cdc.gov/nceh/NewbornScreening or
http://www.cdc.gov/nceh/dls/nsqap.htm

Use of trade names and commercial sources is for identification only and does not imply endorsement by the U.S. Department of Health and Human Services or the Association of Public Health Laboratories.

SAFER • HEALTHIER • PEOPLE™

DBS materials for 24 analytes were distributed to participating laboratories (Figures 4–5). This report presents an overview of all phases of the PT program and summarizes all QC data reported in 2005. For biotinidase, GALT, and hemoglobins, QC materials were not distributed because of the limited availability of appropriate blood sources.

NEW ACTIVITIES

In January 2005, the MS/MS analytes were merged with our overall scheme. Participants were able to report PT results for a total of 21 analytes online.

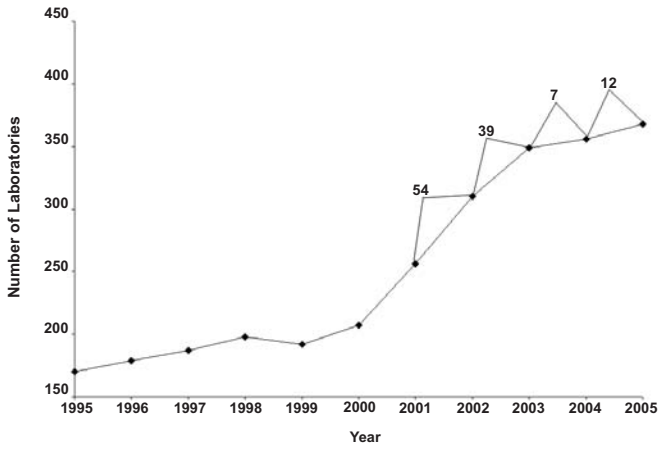
In January 2005, we participated in Genomics Day 2005: Public Health Genomics at CDC, a special event that reviewed ongoing CDC activities in human genomics.

In March 2005, we began posting Sickle Cell (Hemoglobins) and Cystic Fibrosis (IRT/DNA) reports for quarterly proficiency testing events online at http://www.cdc.gov/labstandards/nsqap.htm. Data for these programs were reported by faxed data forms, not online.

In May 2005, we presented a Web conference on *Unsatisfactory Newborn Screening Specimens; Interpretations, Studies and Current Trends* via the Internet. The Web conference presentation is posted for continuing education on the NSQAP Web site at http://www.cdc.gov/nceh/dls/newborn_screening.htm.

In June 2005, NSQAP was awarded the 2005 Charles C. Shepard Science Award. CDC's preeminent science awards were inaugurated in 1986. Each year, the Shepard Awards are presented to a program recognized for out-

FIGURE 1. Laboratory Participation in the Newborn Screening Quality Assurance Program, 1995-2005



standing scientific contribution to public health and to the authors of the most outstanding peer-reviewed research papers published by CDC scientists.

In August 2005, NSQAP staff moved into a state-of-the-art laboratory facility, which was built with an environmental focus using the latest design and technology to save energy and money. For many years, NSQAP was housed in either old World War II barracks or a temporary building. The new lab building ushers in a new era for NSQAP and the other branches of CDC's Division of Laboratory Sciences.

In October 2005, NSQAP launched a pilot PT program for laboratories testing DBS for IgM and IgG antibodies to *Toxoplasma gondii*. Most participants were from outside the United States. Quarterly reports for this pilot program can be found online at http://www.cdc.gov/labstandards/nsqap.htm.

NSQAP cosponsored the 2005 Newborn Screening and Genetic Testing Symposium, October 24-27, 2005. The conference was held at the Hilton Portland and Executive Tower, Portland, Oregon, and was preceded by half-day workshops on QA/QC and Follow-up. Almost 400 laboratorians and follow-up professionals attended from 47 states and 14 countries.

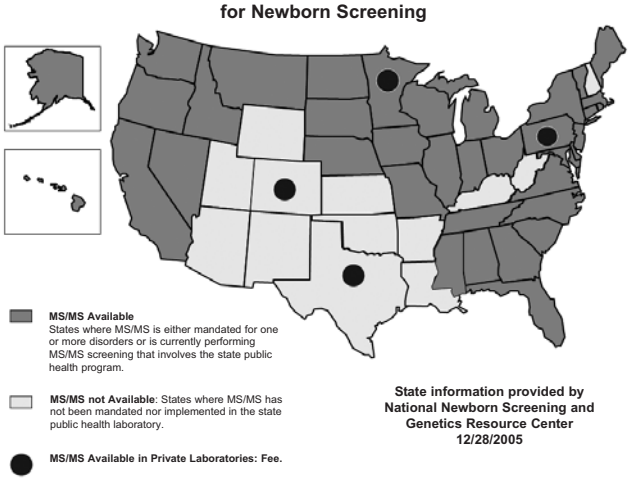
FIGURE 2. Fifty-three Countries Participated in the Newborn Screening Quality Assurance Program in 2005

Participant

Argentina	Greenland	Portugal
Armenia	Guatemala	Russia
Australia	Hungary	Saudi Arabia
Austria	Iceland	South Africa
Belgium	India	South Korea
Brazil	Ireland	Spain
Canada	Italy	Sweden
Chile	Japan	Switzerland
China	Latvia	Taiwan
Colombia	Lebanon	Thailand
Costa Rica	Lithuania	Turkey
Cuba	Luxembourg	Ukraine
Czech Republic	Malaysia	United Kingdom
Denmark	Mexico	United States
Estonia	Netherlands	Uruguay
Finland	New Zealand	Vietnam
France	Philippines	
Germany	Poland	
Greece		

One or more laboratories represented for each country listed.

FIGURE 3. States Using Tandem MS/MS for Newborn Screening



At the NCEH/ATSDR 2005 Honor Awards Ceremony in October 2005, NSQAP was presented the group award for outstanding contributions to management using web-based interactive systems for newborn screening laboratories worldwide.

NSQAP collaborated with Health Resources and Services Administration, National Institutes of Health, American College of Medical Genetics, and Genzyme to present a workshop on *Issues in Presymtomatic Diagnosis of Lysosomal Storage Disorders*, December 6-7, 2005, at the Marriott Bethesda North Hotel and Conference Center, Bethesda, Maryland. The workshop was hosted by National Newborn Screening and Genetics Resources Center. Recommendations emerged from the 84 participants on how to implement screening for lysosomal storage disorders.

NSQAP conducted the second annual proficiency test challenge to qualify laboratories as official testing sites for The Environmental Determinants of Diabetes in the Young (TEDDY) project. Since screening began in 2004, TEDDY investigators have screened over 50,000 newborns and identified over 1000 whose HLA genotypes put them at higher risk for type 1 diabetes.

NSQAP continued development of a reference DBS material for the T-cell Recombination Excision Circle (TREC) assay, which can detect severe combined immunodeficiency disorder (SCID) in the newborn. SCID is a lethal condition of infancy, but affected babies identified before symptoms appear may be saved by hematopoietic stem cell transplants.

FIGURE 4. Number of Participants in Proficiency Testing Programs, 2005
Total = 308

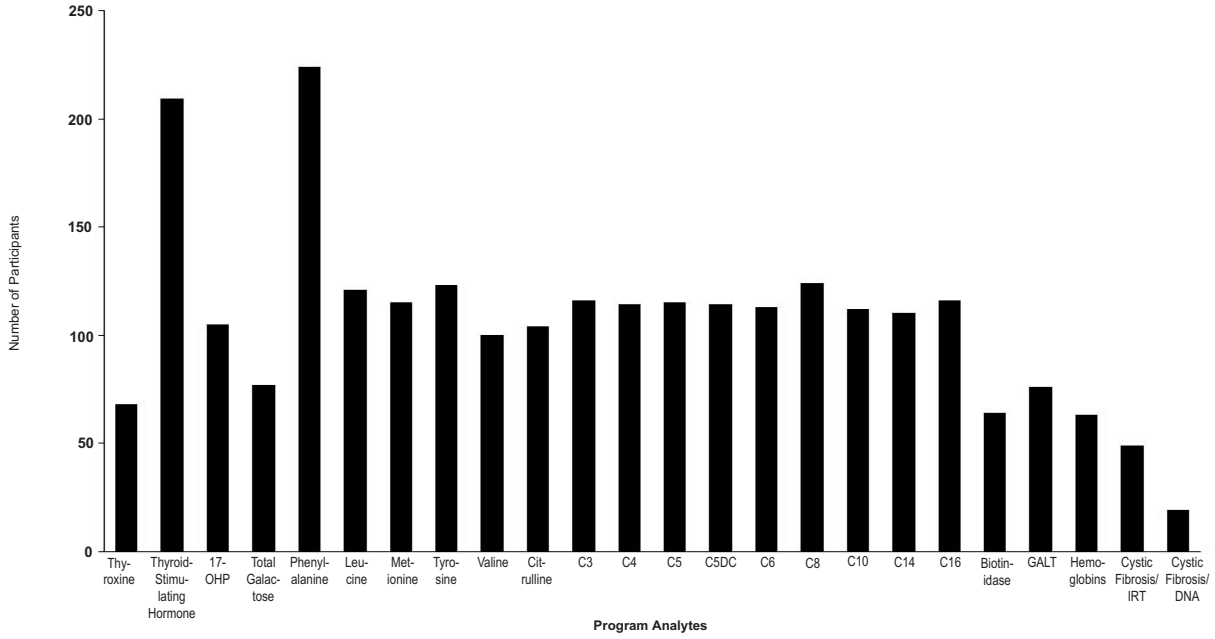
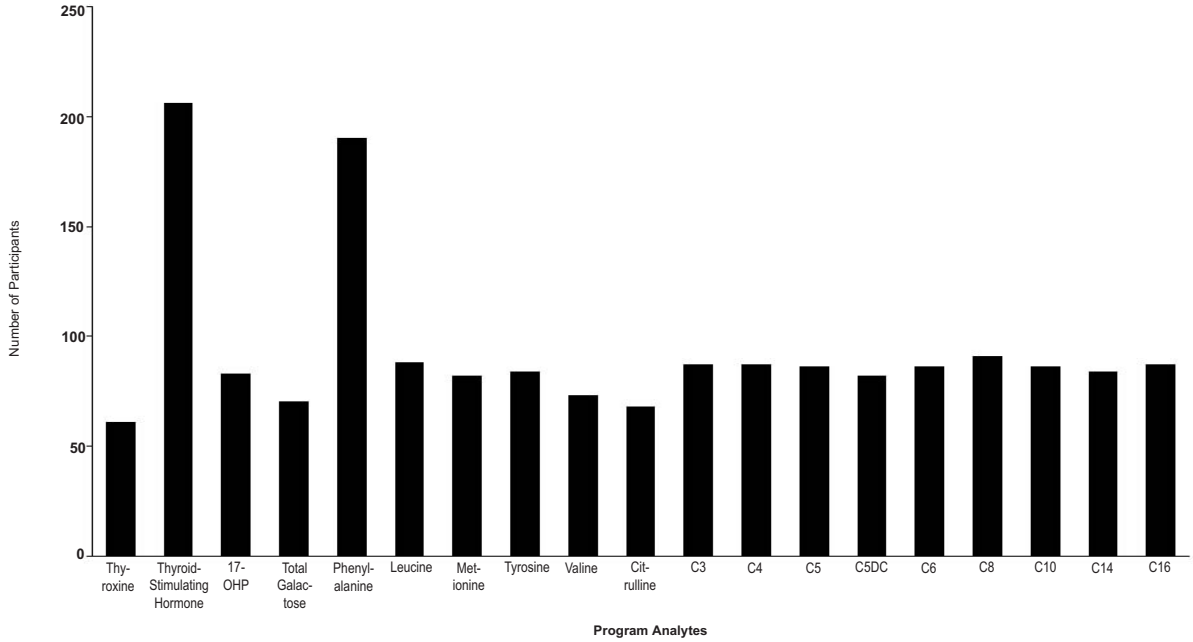


FIGURE 5. Number of Participants in Quality Control Programs, 2005
Total = 295



New investment in public health.....through the CDC Foundation, NSQAP received $118,800 from the National Alliance for Autism Research to study *Immune Biomarkers in Serum and Newborn Dried Blood Spots*.

FILTER PAPER

The paper disk punched to aliquot DBS specimens is a volumetric measurement and requires a degree of uniformity among and within production lots. As part of the QA program, we used an isotopic method[1] developed at CDC to evaluate and compare different lots of filter paper. Mean counts per minute of added isotope-labeled thyroxine (T_4) within a 1/8-inch disk were equated with the serum volume of the disks from the dried whole blood specimens. In comparing production lots, we used statistical analyses of the counting data to determine values for homogeneity and serum absorption of the disks. Lysed-cell whole blood was used initially to avoid variability contributed by uncontrolled red blood cell (RBC) lysis during the 4-day QC production span. Filter paper evaluation studies conformed by using the same lysed-cell whole blood matrix. Results of later studies concluded that RBC lysis occuring during processing of the intact blood pools was not sufficient to contribute substantially to the variance. However, the mean serum volume per disk differs with intact-cell blood. For historical reference and for maintaining uniformity of testing on all the paper production lots, we have continued using the lysed-cell procedure (Figure 6). We also measure performance with intact-cell preparations (Figure 7). The published and standardized acceptable volumes per 1/8-inch disk are 1.30 ± 0.19 µL (mean value and 95% confidence interval [CI]) for lysed-cell blood and 1.54 ± 0.17 µL for intact-cell blood.[1] The mean values and CIs are the filter-paper evaluation parameters published in the Clinical and Laboratory Standards Institute (CLSI), formerly NCCLS-approved standard.[1] The second mean value (solid line) is the mean value produced from the NSQAP database, which was added for reference. The mean values for all lots are within the 95% CI defined by CLSI but are below the mean values indicated by the CLSI standard.[1] In 2002, the mean value and CI for the intact-cell measurements were examined and discussed during a routinely scheduled review period for revision of the NCCLS standard. The CLSI committee retained the original values, which were not produced at CDC, in the revised standard.

Laboratory participation has grown 44% in five years.

Filter paper lots used in the CDC production of QC and PT specimens distributed in 2005 were W001 and W011 of Grade 903. All filter paper lots were analyzed for agreement with the evaluation parameters according to the CLSI-approved standard.[1]

Each year, with the extensive cooperation of the manufacturer (Whatman Inc.) of filter paper approved by the Food and Drug Administration (FDA) for blood collection, we have routinely evaluated new lots and compared new lots with previous lots. The criteria for acceptable performance are the approved limits established in the CLSI standard.[1] A manufacturer also is expected to establish its own testing program using the CLSI standard and make available to the user its certification data for each distributed lot of paper. The independent evaluations by CDC are an impartial and voluntary service offered as a function of our QA program and do not constitute preferential endorsement of any product over other specimen collection papers approved by the FDA.

The serum-absorbance volumes of 21 lots of Grade 903 filter paper (Whatman Inc., Fairfield, NJ) determined from lysed RBCs and for 11 lots determined from intact RBCs, are shown in chronological order. For W041, the most recent production lot of Grade 903 filter paper, we found the mean serum-absorbance volume was 1.35 µL for a 1/8-inch disk for lysed-cell blood and 1.44 µL per 1/8-inch disk for intact-cell blood. Each mean value is within the acceptable range for the matrix used. Lot W041 was homogeneous (i.e., the measured within-spot,

Filter paper lots used in the CDC production of QC and PT specimens distributed in 2005 were W001 and W011 of Grade 903.

FIGURE 6. Whatman 903® Specimen Collection Paper
Serum Volume by Lot Number - Lysed Red Blood Cells

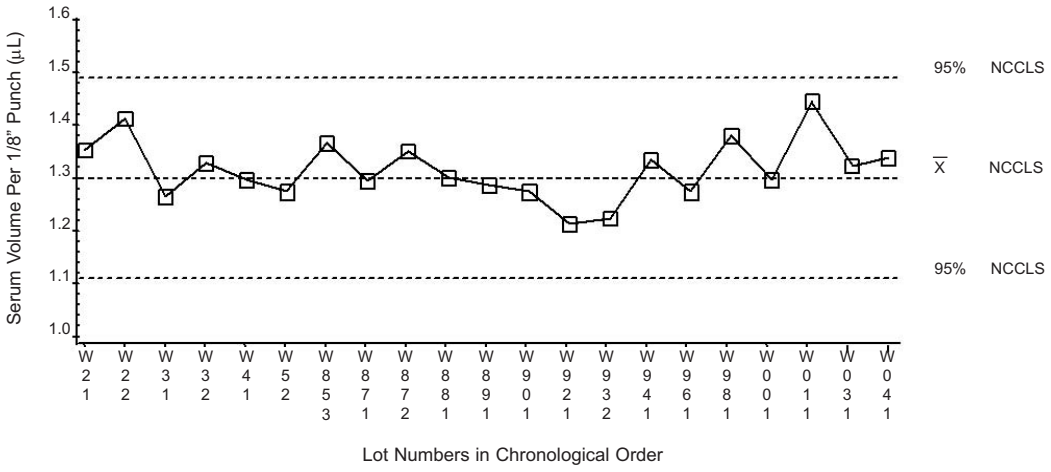
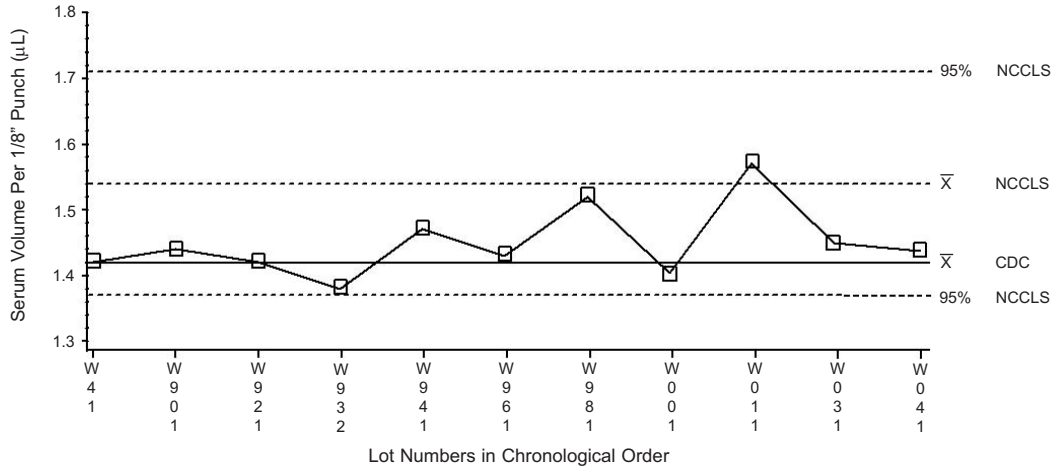


FIGURE 7. Whatman 903® Specimen Collection Paper
Serum Volume by Lot Number - Intact Red Blood Cells

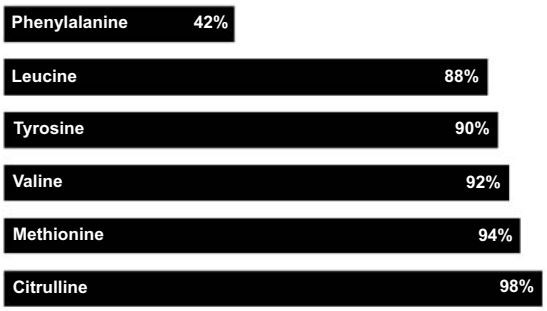


within-sheet, and among-sheets variances were within the acceptable limits). Our data for a production lot depends on the filter paper sample, which the manufacturer provides, being representative of the entire production batch, i.e., statistically valid sampling.

SPECIMEN PREPARATION AND DATA HANDLING

Tables and figures show the enriched concentrations of PT specimens and QC lots as well as the summarized quantitative data. The total concentration of each specimen or lot equaled the sum of the enriched concentration and the endogenous concentration (nonenriched). For thyroxine (T_4) PT specimens, the CDC assayed values were reported because of differences in the blood sources used for DBS production. Some specimens were enriched above the endogenous T_4 concentration, and some were enriched with T_4 after T_4 depletion of the base serum. Except for biotinidase and GALT, all DBS specimens in the PT surveys and QC production lots were prepared from whole blood of 55% hematocrit. Purified analytes or natural donor blood, except for thyroid-stimulating hormone (TSH), which used the Second International Reference Preparation (80/558), were used for all enrichments. For galactosemia, enrichments were made with galactose, galactose-1-phosphate, or both so that both free galactose (galactose alone) and total galactose (free galactose plus galactose present as galactose-1-phosphate) could be measured. For biotinidase and GALT, individual donor blood from adults with these disorders was used with the hematocrit adjusted to 50%. All reported analytic values outside the 99% CI were excluded from the summaries of quantitative results.

FIGURE 8. Worldwide Impact of MS/MS on Amino Acids Data Reported to NSQAP in 2005



For obtaining data on the QC materials, we estimated the method response to endogenous materials by performing weighted linear regression analyses for mean-reported concentrations versus enriched concentrations. We then extrapolated the regression lines to the Y-axis to obtain an estimate of the observed endogenous analyte concentration for each method category. These estimates are reliable when (1) enrichments are accurate, (2) the analytic method gives a linear response across the range of the measurements, and (3) the slopes for regression lines are approximately equal to one.

In 2005, we applied the laboratory-reported specific cutoff values, when available, to our grading algorithm for clinical assessments; otherwise, we used the NSQAP-assigned working cutoff values based on the national mean value for this assessment.

CUTOFFS

When reporting cutoff values, we requested the decision level for sorting test results reported as presumptive positive (outside limits) from results reported as negative (within limits). The reported cutoff values are summarized in Tables 1 and 2 for domestic and foreign laboratories. The values for mean (arithmetic average), median (middle value), and mode (most frequent value) are shown for each analyte. The mean cutoff values for domestic and foreign laboratories are similar except those for 17 α-hydroxyprogesterone (17-OHP), which are twice as high for domestic laboratories and those for immunoreactive trypsinogen (IRT), which are 25% higher for domestic laboratories. The range (min/max) of cutoff values is large for TSH, 17-OHP, total galactose (Gal), IRT, C3, and C16 for both domestic and foreign laboratories. The mean and median of cutoff values for the MS/MS amino acids are the same for domestic and foreign laboratories; however, the range is larger for foreign laboratories. Mean cutoff values for phenylalanine (Phe), leucine (Leu), methionine (Met), tyrosine (Tyr), valine (Val), citrulline (Cit), C5 and C5DC are almost identical for domestic and foreign laboratories.

PROFICIENCY TESTING

All PT panels contained five blind-coded 75-µL or 100-µL DBS specimens. Specimens in the PT panels either contained endogenous levels or were enriched with predetermined levels of T_4, TSH, 17-OHP, Gal, Phe, Leu, Met, Tyr, Val, Cit, and acylcarnitines (C3, C4, C5, C5DC, C6, C8, C10, C14, C16). Specimens for the CF panel were prepared with DNA from Epstein-Barr virus-transformed lymphoblastoid cell lines homozygous or heterozygous for ΔF508 in sheep or human whole blood matrix

TABLE 1. 2005 Summary of MS/MS Cutoff Values of Domestic and Foreign Laboratories

Domestic

Analyte	N	Mean	Median	Mode	Min/Max
Phenylalanine	35	2.4	2.3	2.3	1.8-3.6
Leucine	36	3.7	3.9	2.6	2.6-6.0
Methionine	35	1.3	1.3	1.5	0.7-2.0
Tyrosine	32	7.8	7.2	12.7	1.6-12.7
Valine	27	3.3	3.2	3.2	2.3-4.4
Citrulline	34	1.1	1.1	1.1	0.4-1.8
C3	37	6.97	7.00	9.25	1.20-10.43
C4	37	1.47	1.57	1.80	0.44-2.50
C5	37	0.85	0.86	1.20	0.32-1.20
C5DC	37	0.27	0.30	0.35	0.09-0.50
C6	36	0.52	0.57	0.70	0.16-1.05
C8	41	0.48	0.50	0.50	0.17-1.00
C10	36	0.54	0.53	0.60	0.24-1.21
C14	33	0.82	0.80	1.10	0.17-1.10
C16	34	8.52	9.00	10.00	0.41-11.23

Foreign

Analyte	N	Mean	Median	Mode	Min/Max
Phenylalanine	78	2.4	2.3	2.5	1.1-4.0
Leucine	69	4.3	4.1	3.9	2.0-7.0
Methionine	68	1.0	0.9	0.9	0.4-2.7
Tyrosine	76	5.7	5.6	6.3	1.4-15.0
Valine	61	3.5	3.5	3.5	1.7-6.9
Citrulline	64	1.1	1.0	0.9	0.3-2.6
C3	72	6.00	6.00	6.00	2.60-10.00
C4	70	1.29	1.28	1.00	0.40-5.00
C5	72	0.82	0.64	0.60	0.18-3.30
C5DC	71	0.28	0.20	0.20	0.09-1.70
C6	71	0.44	0.40	0.21	0.10-2.03
C8	77	0.42	0.42	0.50	0.14-1.05
C10	69	0.47	0.43	0.50	0.14-1.20
C14	70	0.77	0.70	0.50	0.19-1.66
C16	72	7.85	8.00	8.00	2.10-14.00

enriched with IRT. Special separate panels for biotinidase deficiency and for GALT deficiency were prepared with purchased blood from donors with enzyme deficiencies. Specimens for the hemoglobinopathies panel were prepared from umbilical cord blood.

Specimen sets were packaged in a zip-close metallized plastic bag with desiccant, instructions for analysis, and data-report forms for laboratories that did not report data by Internet. We prepared and distributed quarterly reports of all results that had been received by the deadline dates. In this annual report, the comparisons of results by different methods (Figures 9–28) are illustrated with the participants' reported PT data for one selected challenge for each analyte during the year. These are compared using bias plots that show the difference (positive or negative) by laboratory and method of the reported value subtracted from the expected value (CDC-measured endogenous level plus enrichment) and for IRT and C5DC, the reported value subtracted from the CDC assayed value. When examining the bias plots, note the scale-changes of the Y-axis relative to the expected value for each plot. A reported value matching the expected value will show the illustrated value as falling on the "0" line of the plot. A reasonable bias is less than ± 20% of the expected value. A summary of the specimen data for selected-quarter PT challenges in 2005 is tabulated in the left margin for each figure. All T_4 specimens were enriched with 4.0 µg/dL of

T_4 but have different CDC assayed values (Figure 9) because some specimens were prepared from T_4-depleted base pools and others from normal untreated base pools. A base pool is a serum pool prepared by mixing serum from normal donors. The selected normal base pools had different endogenous T_4 levels. This process yields specimens with different values from a common enrichment.

OHP. The "other" method group showed the greatest scatter of values among users for both analytes. For the predominately used TSH and 17-OHP methods, the values were reasonably consistent, although the TSH showed some negative bias while 17-OHP showed a positive bias. Comparisons of values for most methods for Gal showed agreement close to the expected value (Figure 12). For

TABLE 2. 2005 Summary of Non-MS/MS Cutoff Values of Domestic and Foreign Laboratories

Domestic

Analyte	N	Mean	Median	Mode	Min/Max
T4	28	6.1	6.0	6.0	3.5-8.0
TSH	46	32.1	25.0	20.0	19.4-61
17-OHP	38	62.2	56.5	87.6	25-88
Galactose	22	11.2	10.0	10.0	5-25
Phenylalanine	24	2.7	2.5	2.1	2-4
Leucine	1	4.9	4.9	--	--
Methionine	1	1.5	1.5	--	--
Tyrosine	4	5.0	5.1	--	2.5-7.5
Valine	2	3.7	3.7	--	3.5-3.8
IRT	9	95.3	105.0	105.0	63-170

Foreign

Analyte	N	Mean	Median	Mode	Min/Max
T4	27	6.5	6.0	6.0	4.0-13.8
TSH	142	24.9	22.0	20.0	2.2-50
17-OHP	56	28.7	27.5	22.0	7.0-90
Galactose	47	11.8	10.0	10.0	5.0-27.3
Phenylalanine	71	3.0	3.0	4.0	1.8-5.0
Leucine	5	3.4	3.0	2.0	2-5.8
Methionine	2	3.5	3.0	--	1-6.0
Tyrosine	2	3.3	3.3	--	3-3.6
Valine	1	2.5	2.5	--	--
IRT	37	76.2	70.0	70.0	50-300

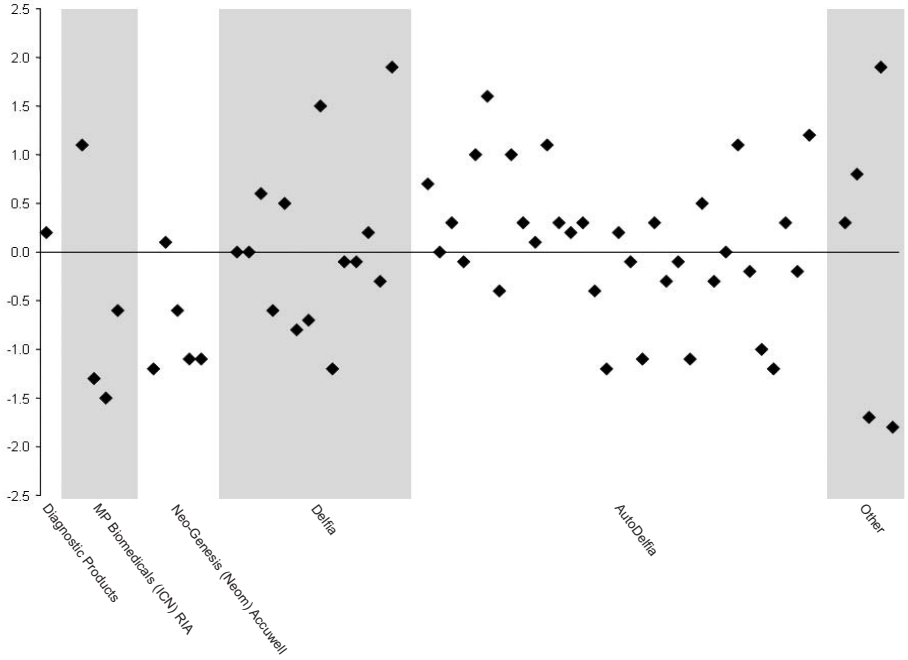
The representative specimens selected for the bias plots (Figures 9–28) were either above or below the cutoff value for the analyte. In general, the quantitative comparisons (Figures 9–28) for PT challenges are reasonable within a method but vary among methods. The PT quantitative results are grouped by kit or method to illustrate any method-related differences in analyte recoveries. Because some of the pools in a routine PT survey represent a unique donor specimen, differences in endogenous materials in the donor specimens may influence method-related differences. The scatter of values for T_4 (Figure 9) was large and fairly consistent among methods. The TSH and 17-OHP results (Figures 10 and 11) performed consistently among the different methods, with several methods showing some higher values for TSH and 17-

Phe (Figure 13), the reported results showed high variability within and among methods. One Phe method showed variability among users with a predominately negative bias with the expected value. The values reported for Leu (Figure 14) showed reasonable variability with two methods contributing most of the high variability. One Leu method showed close agreement with the expected value and low variability among most users. Three methods for Met (Figure 15) produced lower values than the others with a consistent negative bias, and another method showed close agreement with the expected value. The most commonly used Met method showed a negative variance scatter around the expected value that was not seen in the 2004 report. For Tyr (Figure 16), all methods showed a large scatter of values and a predomi-

FIGURES 9-10. Reproducibility of Results by Different Methods - Thyroxine and Thyroid-Stimulating Hormone

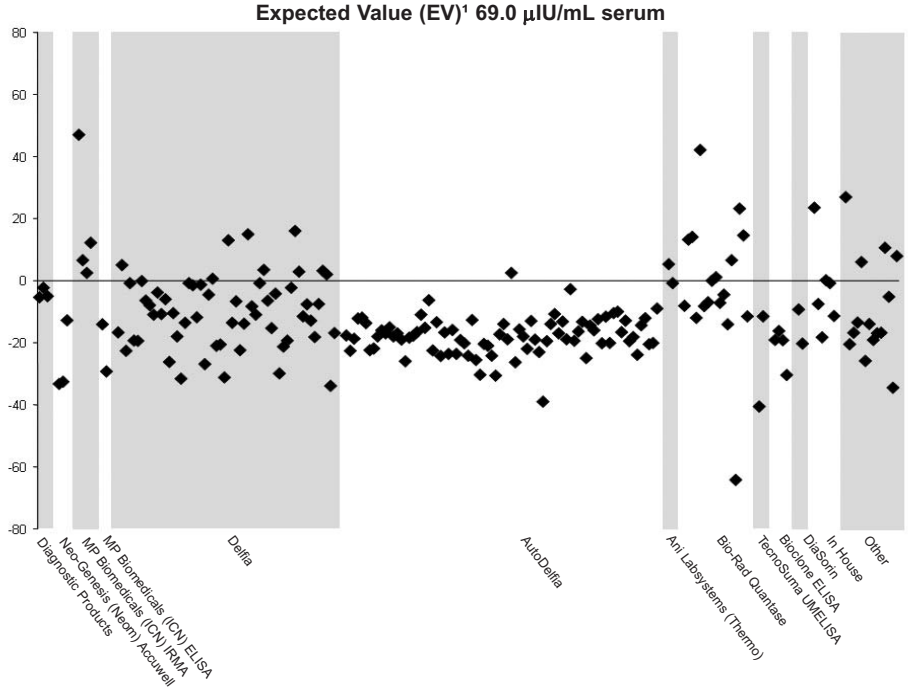
	Quarter 1
Specimen 1	
Enriched	4
CDC Assayed	3.5
Participant Mean	3
Specimen 2	
Enriched	4.2
CDC Assayed	5.1
Participant Mean	4.3
Specimen 3	
Enriched	4
CDC Assayed	4.8
Participant Mean	4
CDC Bias[2]	0.8
Participant Bias[3]	0
Specimen 4	
Enriched	4
CDC Assayed	11.6
Participant Mean	8.1
Specimen 5	
Enriched	4
CDC Assayed	19
Participant Mean	16.5

Figure 9. Bias Plot of Thyroxine Values by Method
Quarter 1, Specimen 3
Expected Value (EV)[1] 4.0 µg/dL serum



	Quarter 1
Specimen 1	
Enriched	65
CDC Assayed	65
Participant Mean	55.7
CDC Bias[2]	-4
Participant Bias[3]	-13.3
Specimen 2	
Enriched	31.5
CDC Assayed	34
Participant Mean	38.8
Specimen 3	
Enriched	75
CDC Assayed	87
Participant Mean	81.1
Specimen 4	
Enriched	9
CDC Assayed	14
Participant Mean	8.5
Specimen 5	
Enriched	9
CDC Assayed	4.8
Participant Mean	5.9

Figure 10. Bias Plot of Thyroid-Stimulating Hormone Values by Method
Quarter 1, Specimen 1
Expected Value (EV)[1] 69.0 µIU/mL serum

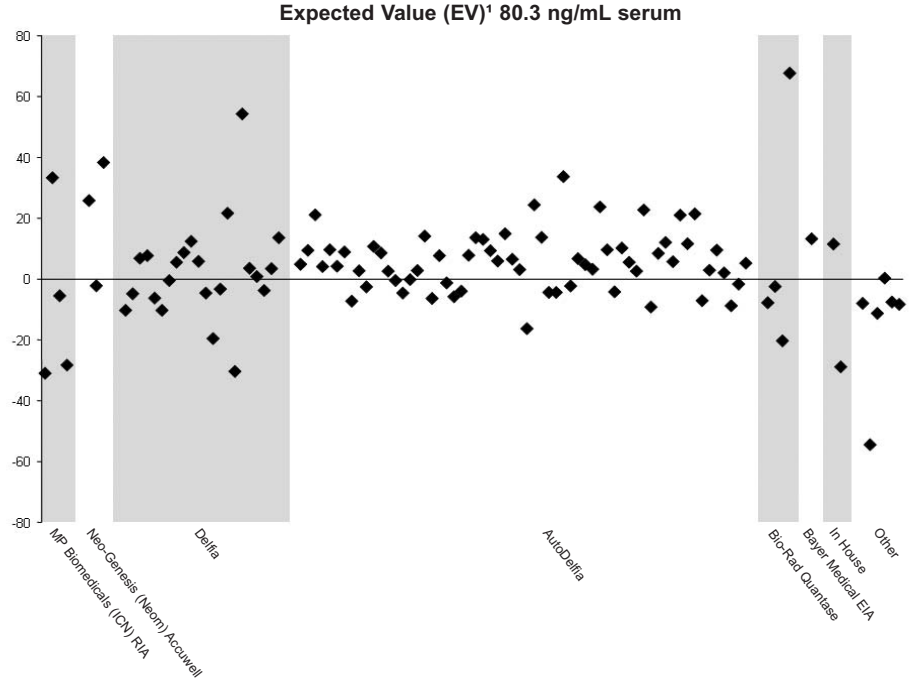


[1]EV is the sum of the endogenous and enrichment values. The solid line represents perfect agreement with the EV or zero bias.
[2]± CDC bias is the CDC assayed value minus EV.
[3]± Participant bias is the Participant mean assayed value minus EV. The Participant mean excludes outlier values.

FIGURES 11-12. Reproducibility of Results by Different Methods - 17 α-Hydroxyprogesterone and Total Galactose

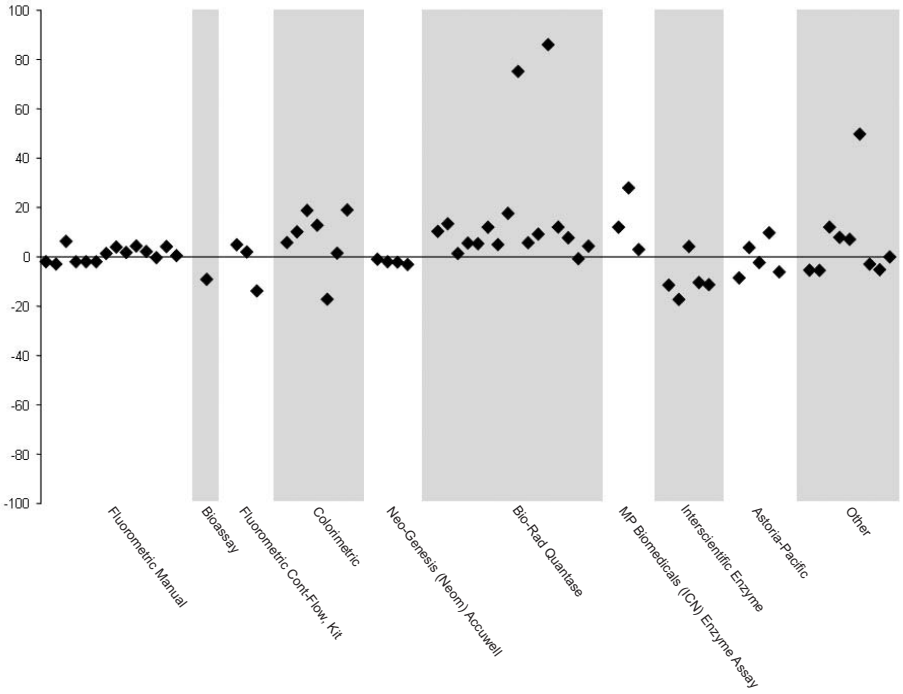
	Quarter 3
Specimen 1	
Enriched	80
CDC Assayed	56
Participant Mean	78.4
Specimen 2	
Enriched	70
CDC Assayed	66.2
Participant Mean	80.9
Specimen 3	
Enriched	0
CDC Assayed	0
Participant Mean	0.9
Specimen 4	
Enriched	80
CDC Assayed	74.6
Participant Mean	83.7
CDC Bias[2]	-5.7
Participant Bias[3]	3.4
Specimen 5	
Enriched	0
CDC Assayed	0
Participant Mean	1.4

Figure 11. Bias Plot of 17 α-Hydroxyprogesterone Values by Method
Quarter 3, Specimen 4
Expected Value (EV)[1] 80.3 ng/mL serum



	Quarter 2
Specimen 1	
Enriched	30
CDC Assayed	31.5
Participant Mean	34.3
CDC Bias[2]	-0.5
Participant Bias[3]	2.3
Specimen 2	
Enriched	0
CDC Assayed	1.9
Participant Mean	2.1
Specimen 3	
Enriched	0
CDC Assayed	1.2
Participant Mean	2.1
Specimen 4	
Enriched	0
CDC Assayed	0
Participant Mean	1.7
Specimen 5	
Enriched	30
CDC Assayed	31.8
Participant Mean	33.9

Figure 12. Bias Plot of Total Galactose Values by Method
Quarter 2, Specimen 1
Expected Value (EV)[1] 32.0 mg/dL whole blood

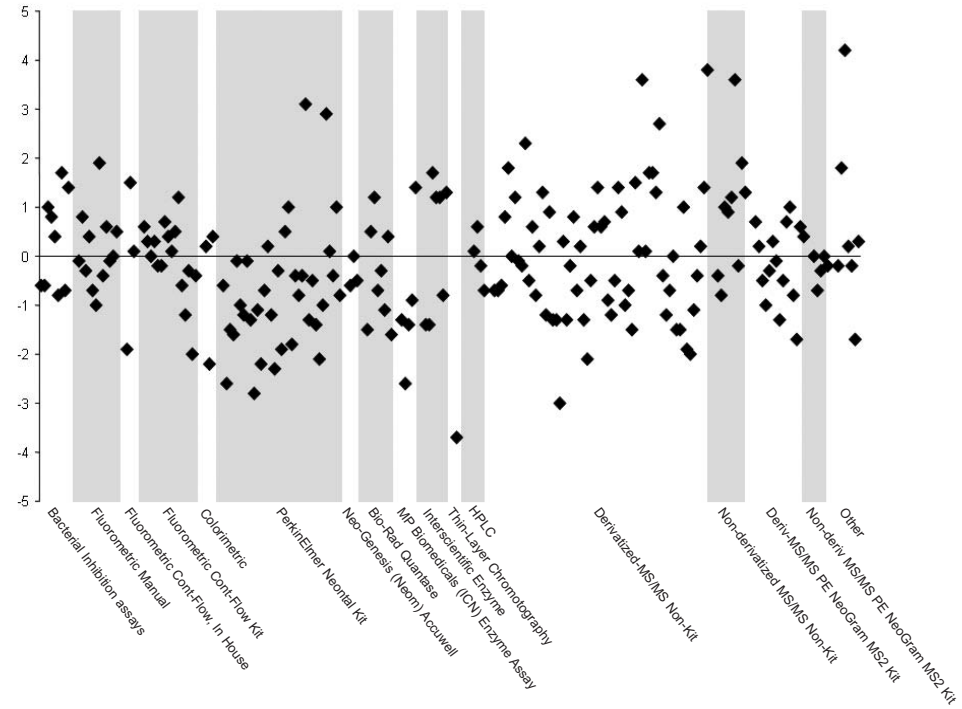


[1]EV is the sum of the endogenous and enrichment values. The solid line represents perfect agreement with the EV or zero bias.
[2]± CDC bias is the CDC assayed value minus EV.
[3]± Participant bias is the Participant mean assayed value minus EV. The Participant mean excludes outlier values.

FIGURES 13-14. Reproducibility of Results by Different Methods - Phenylalanine and Leucine

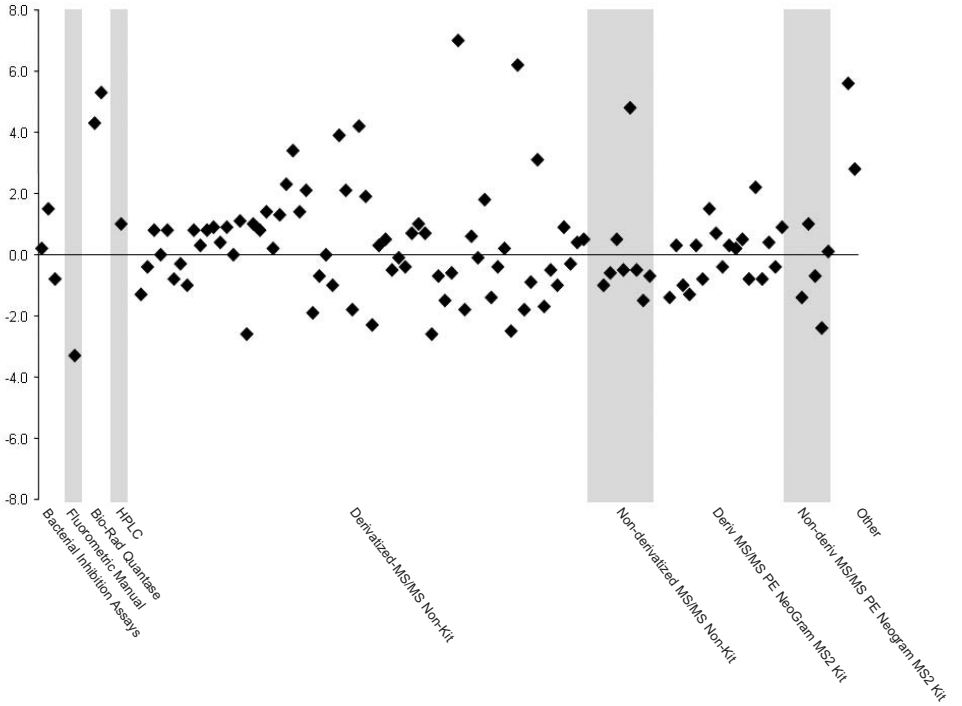
	Quarter 1
Specimen 1	
Enriched	0
CDC Assayed	0.9
Participant Mean	1.1
Specimen 2	
Enriched	0
CDC Assayed	1.1
Participant Mean	1.3
Specimen 3	
Enriched	5.5
CDC Assayed	6.4
Participant Mean	6.4
CDC Bias[2]	-0.2
Participant Bias[3]	-0.2
Specimen 4	
Enriched	0
CDC Assayed	1
Participant Mean	1.1
Specimen 5	
Enriched	0
CDC Assayed	1.3
Participant Mean	1.3

Figure 13. Bias Plot of Phenylalanine Values by Method
Quarter 1, Specimen 3
Expected Value (EV)[1] 6.6 mg/dL whole blood



	Quarter 2
Specimen 1	
Enriched	0
CDC Assayed	1.8
Participant Mean	2
Specimen 2	
Enriched	0
CDC Assayed	2.2
Participant Mean	2.1
Specimen 3	
Enriched	5.5
CDC Assayed	7.7
Participant Mean	7.8
CDC Bias[2]	-0.1
Participant Bias[3]	0
Specimen 4	
Enriched	0
CDC Assayed	2.9
Participant Mean	2.5
Specimen 5	
Enriched	0
CDC Assayed	2.2
Participant Mean	2.1

Figure 14. Bias Plot of Leucine Values by Method
Quarter 2, Specimen 3
Expected Value (EV)[1] 7.8 mg/dL whole blood

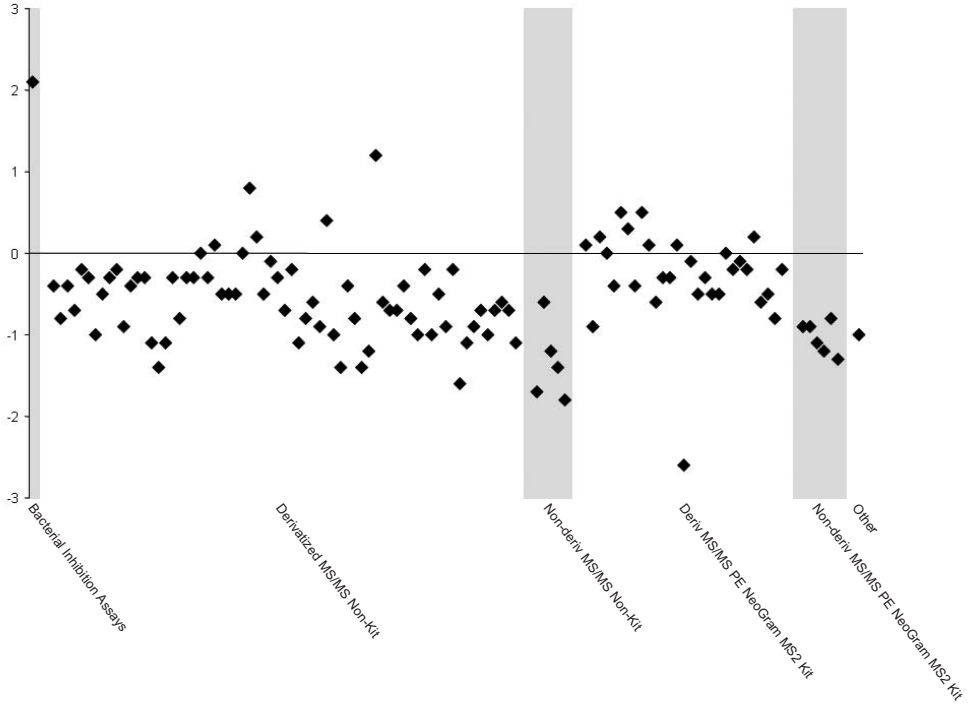


[1]EV is the sum of the endogenous and enrichment values. The solid line represents perfect agreement with the EV or zero bias.
[2]± CDC bias is the CDC assayed value minus EV.
[3]± Participant bias is the Participant mean assayed value minus EV. The Participant mean excludes outlier values.

FIGURES 15-16. Reproducibility of Results by Different Methods - Methionine and Tyrosine

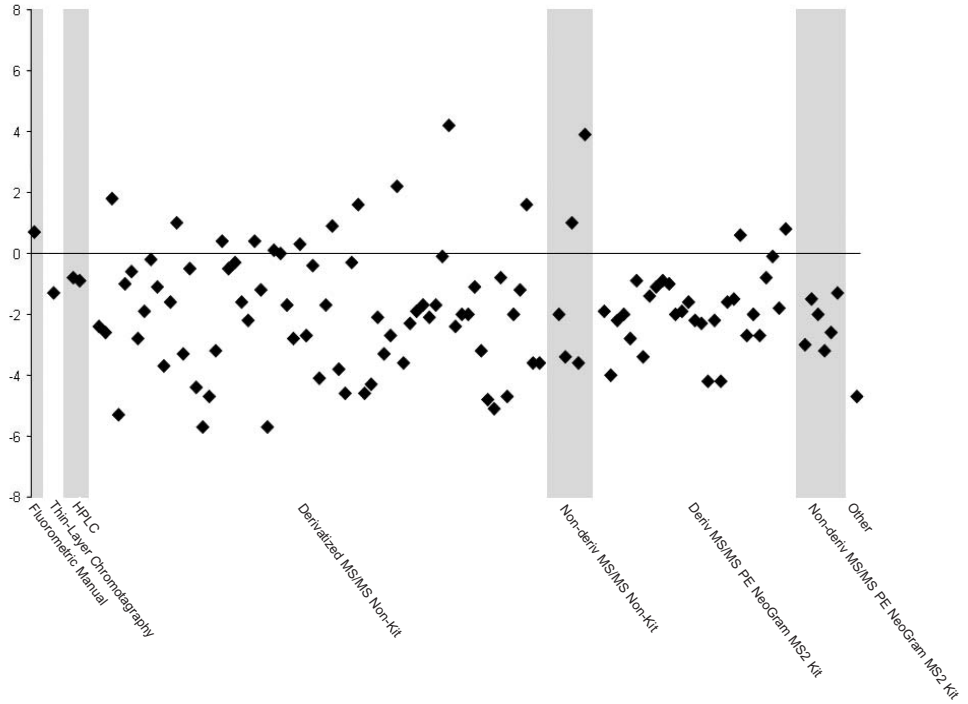
	Quarter 3
Specimen 1	
Enriched	0
CDC Assayed	0.4
Participant Mean	0.3
Specimen 2	
Enriched	0
CDC Assayed	0.4
Participant Mean	0.3
Specimen 3	
Enriched	0
CDC Assayed	0.5
Participant Mean	0.4
Specimen 4	
Enriched	2.5
CDC Assayed	2.7
Participant Mean	2.3
CDC Bias[2]	-0.2
Participant Bias[3]	-0.6
Specimen 5	
Enriched	0
CDC Assayed	0.5
Participant Mean	0.3

Figure 15. Bias Plot of Methionine Values by Method
Quarter 3, Specimen 4
Expected Value (EV)[1] 2.9 mg/dL whole blood



	Quarter 3
Specimen 1	
Enriched	0
CDC Assayed	1.6
Participant Mean	1.3
Specimen 2	
Enriched	10
CDC Assayed	11.8
Participant Mean	9.4
CDC Bias[2]	0.5
Participant Bias[3]	-1.9
Specimen 3	
Enriched	0
CDC Assayed	1.5
Participant Mean	1.2
Specimen 4	
Enriched	0
CDC Assayed	1.6
Participant Mean	1.4
Specimen 5	
Enriched	0
CDC Assayed	1.3
Participant Mean	1.1

Figure 16. Bias Plot of Tyrosine Values by Method
Quarter 3, Specimen 2
Expected Value (EV)[1] 11.3 mg/dL whole blood

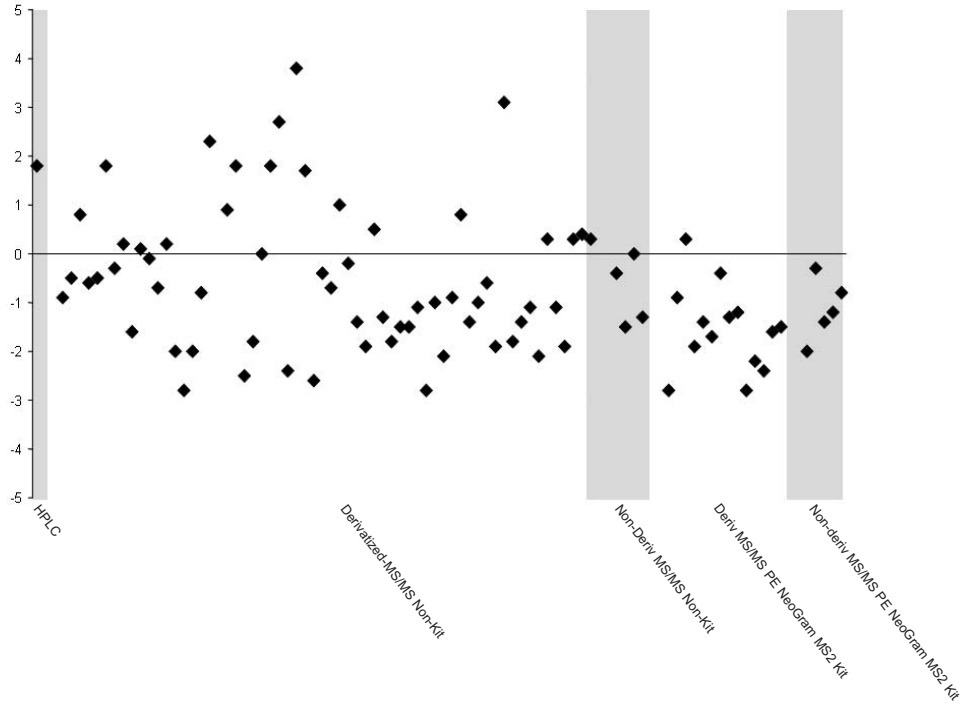


[1]EV is the sum of the endogenous and enrichment values. The solid line represents perfect agreement with the EV or zero bias.
[2]± CDC bias is the CDC assayed value minus EV.
[3]± Participant bias is the Participant mean assayed value minus EV. The Participant mean excludes outlier values.

FIGURES 17-18. Reproducibility of Results by Different Methods - Valine and Citrulline

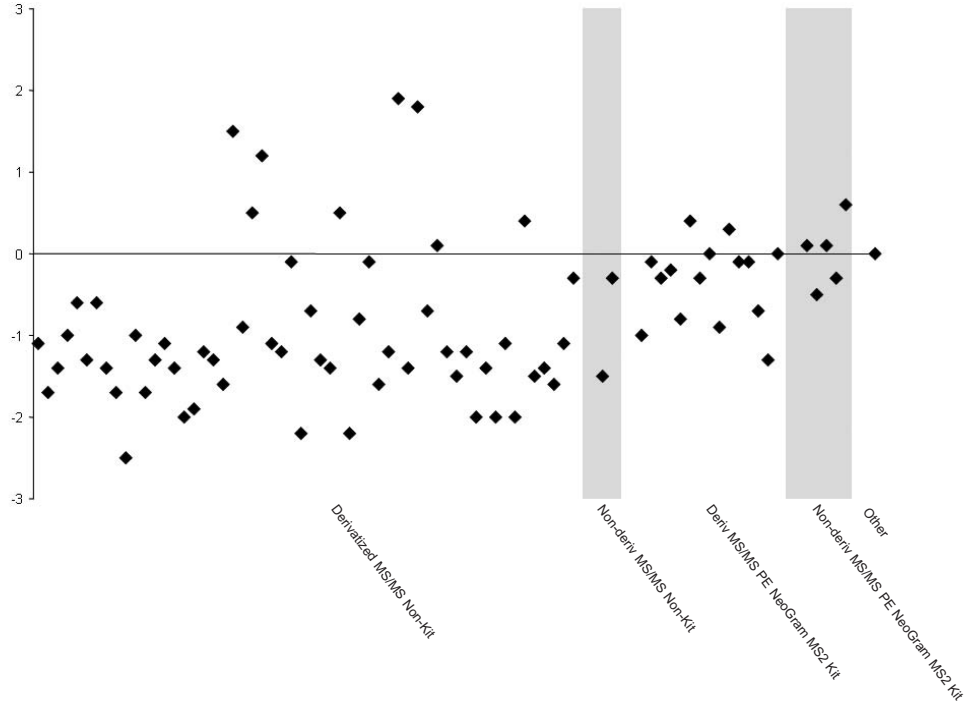
	Quarter 2
Specimen 1	
Enriched	0
CDC Assayed	1.5
Participant Mean	1.7
Specimen 2	
Enriched	10
CDC Assayed	1.8
Participant Mean	1.9
Specimen 3	
Enriched	4.5
CDC Assayed	5.9
Participant Mean	5.9
CDC Bias[2]	-0.7
Participant Bias[3]	-0.7
Specimen 4	
Enriched	0
CDC Assayed	2.3
Participant Mean	2.2
Specimen 5	
Enriched	0
CDC Assayed	1.8
Participant Mean	2.5

Figure 17. Bias Plot of Valine Values by Method
Quarter 2, Specimen 3
Expected Value (EV)[1] 6.6 mg/dL whole blood



	Quarter 1
Specimen 1	
Enriched	0
CDC Assayed	0.4
Participant Mean	0.4
Specimen 2	
Enriched	0
CDC Assayed	0.7
Participant Mean	0.6
Specimen 3	
Enriched	0
CDC Assayed	0.6
Participant Mean	0.5
Specimen 4	
Enriched	3
CDC Assayed	2.8
Participant Mean	2.6
CDC Bias[2]	-0.7
Participant Bias[3]	-0.9
Specimen 5	
Enriched	0
CDC Assayed	0.4
Participant Mean	0.4

Figure 18. Bias Plot of Citrulline Values by Method
Quarter 1, Specimen 4
Expected Value (EV)[1] 3.5 mg/dL whole blood

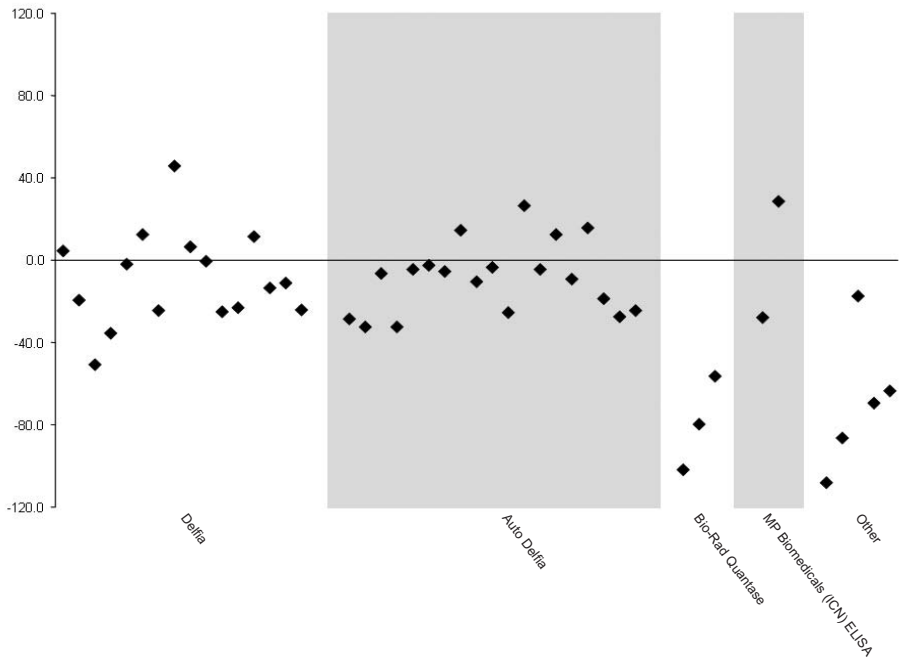


[1]EV is the sum of the endogenous and enrichment values. The solid line represents perfect agreement with the EV or zero bias.
[2]± CDC bias is the CDC assayed value minus EV.
[3]± Participant bias is the Participant mean assayed value minus EV. The Participant mean excludes outlier values.

FIGURES 19-20. Reproducibility of Results by Different Methods - Cystic Fibrosis (IRT) and Propionylcarnitine (C3)

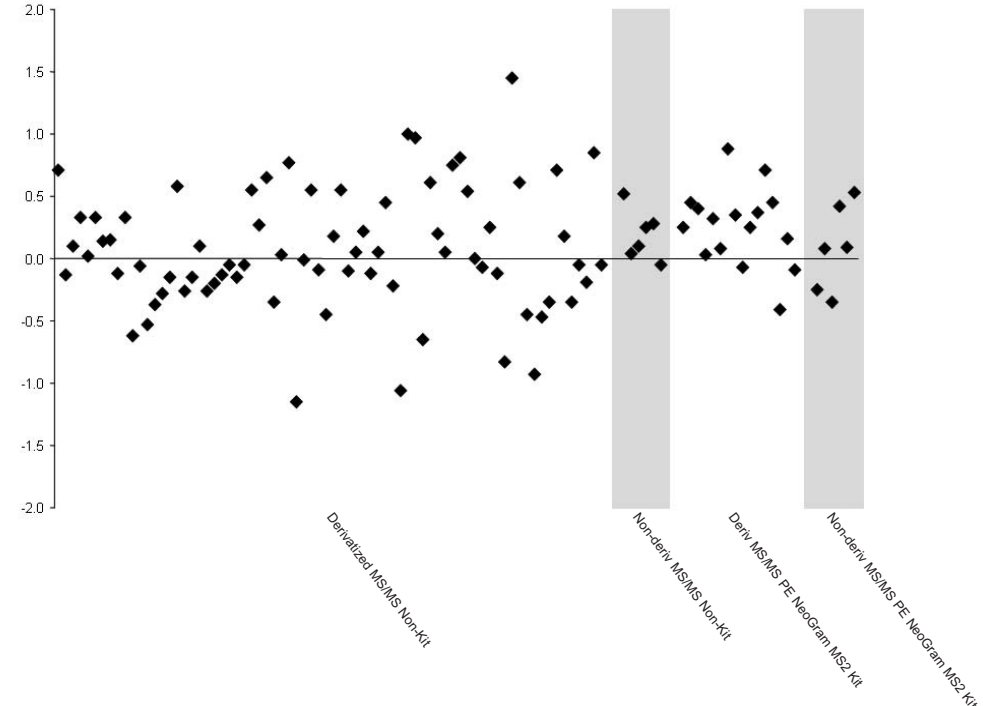
	Quarter 1
Specimen 1	
CDC Assayed	12.6
Participant Mean	9.4
Specimen 2	
CDC Assayed	20.1
Participant Mean	18.4
Specimen 3	
CDC Assayed	15.9
Participant Mean	12.8
Specimen 4	
CDC Assayed	149.5
Participant Mean	133.5
Participant Bias[3]	-16.0
Specimen 5	
CDC Assayed	180.2
Participant Mean	159

Figure 19. Bias Plot of Cystic Fibrosis (IRT) Values by Method
Quarter 1, Specimen 4
Assayed Value (AV)[4] 149.5 ng/mL whole blood



	Quarter 2
Specimen 1	
Enriched	24.00
CDC Assayed	29.42
Participant Mean	26.86
Specimen 2	
Enriched	0
CDC Assayed	2.34
Participant Mean	2.18
Specimen 3	
Enriched	0
CDC Assayed	2.38
Participant Mean	2.36
CDC Bias[2]	0.13
Participant Bias[3]	0.11
Specimen 4	
Enriched	0
CDC Assayed	2.43
Participant Mean	2.37
Specimen 5	
Enriched	12.00
CDC Assayed	17.80
Participant Mean	16.15

Figure 20. Bias Plot of Propionylcarnitine (C3) Values by Method
Quarter 2, Specimen 3
Expected Value (EV)[1] 2.25 µmol/L whole blood

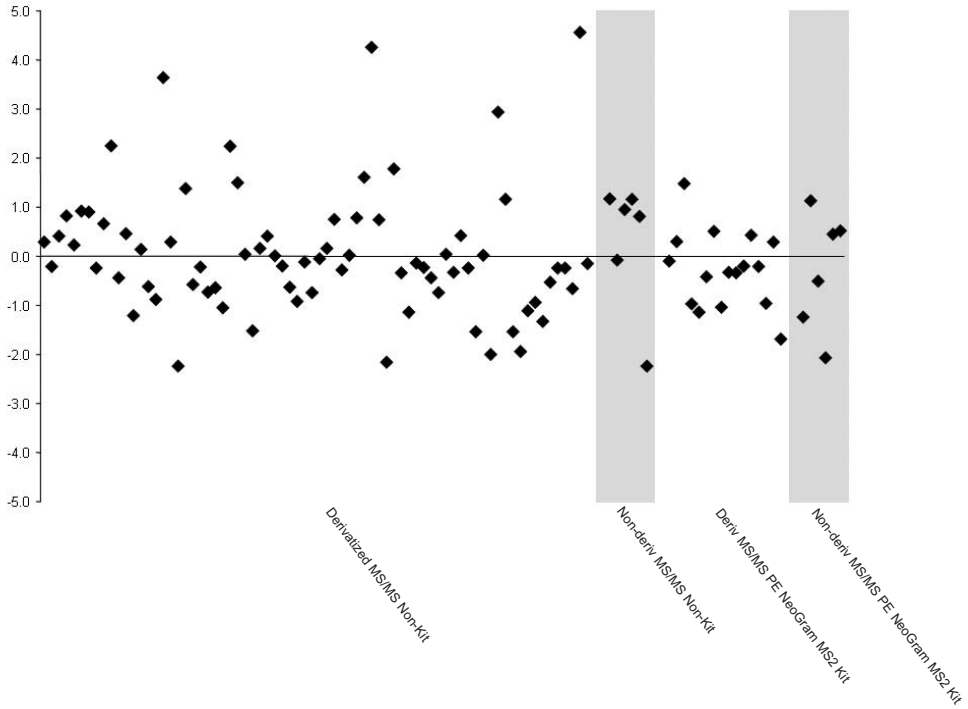


[1]EV is the sum of the endogenous and enrichment values. The solid line represents perfect agreement with the EV or zero bias.
[2]± CDC bias is the CDC assayed value minus EV.
[3]± Participant bias is the Participant mean assayed value minus EV. The Participant mean excludes outlier values.
[4]AV is the CDC assayed value. The solid line represents perfect agreement with the AV or zero bias.

FIGURES 21-22. Reproducibility of Results by Different Methods - Butyrylcarnitine (C4) and Isovalerylcarnitine (C5)

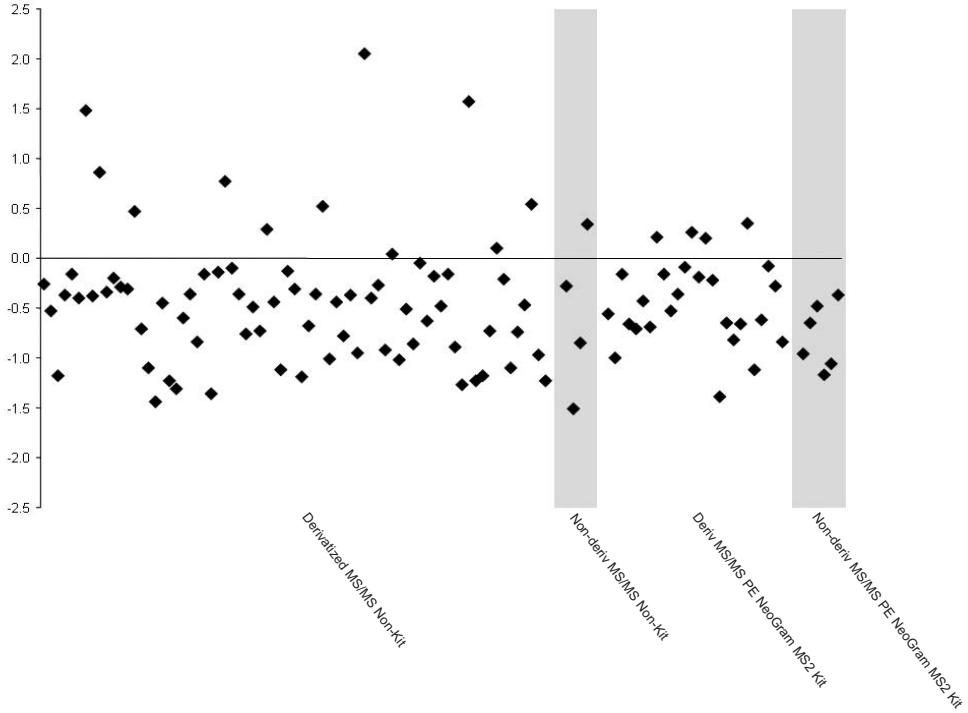
	Quarter 2
Specimen 1	
Enriched	0
CDC Assayed	0.28
Participant Mean	0.33
Specimen 2	
Enriched	10.00
CDC Assayed	8.76
Participant Mean	7.86
Specimen 3	
Enriched	0
CDC Assayed	0.77
Participant Mean	0.61
Specimen 4	
Enriched	3.00
CDC Assayed	2.30
Participant Mean	2.06
Specimen 5	
Enriched	5.00
CDC Assayed	5.37
Participant Mean	5.08
CDC Bias[2]	0.13
Participant Bias[3]	-0.16

Figure 21. Bias Plot of Butyrylcarnitine (C4) Values by Method
Quarter 2, Specimen 5
Expected Value (EV)[1] 5.24 µmol/L whole blood



	Quarter 3
Specimen 1	
Enriched	0
CDC Assayed	0.14
Participant Mean	0.17
Specimen 2	
Enriched	0
CDC Assayed	0.17
Participant Mean	0.18
Specimen 3	
Enriched	3.00
CDC Assayed	2.40
Participant Mean	2.63
CDC Bias[2]	-0.76
Participant Bias[3]	-0.53
Specimen 4	
Enriched	0
CDC Assayed	0.13
Participant Mean	0.18
Specimen 5	
Enriched	12.00
CDC Assayed	9.95
Participant Mean	10.29

Figure 22. Bias Plot of Isovalerylcarnitine (C5) Values by Method
Quarter 3, Specimen 3
Expected Value (EV)[1] 3.16 µmol/L whole blood

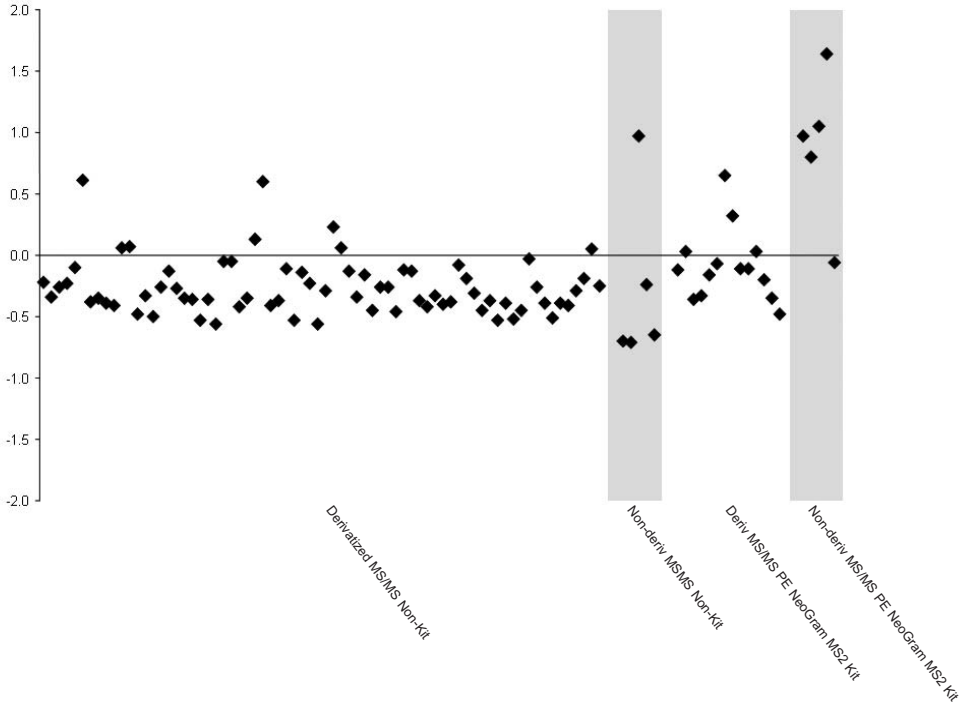


[1]EV is the sum of the endogenous and enrichment values. The solid line represents perfect agreement with the EV or zero bias.
[2]± CDC bias is the CDC assayed value minus EV.
[3]± Participant bias is the Participant mean assayed value minus EV. The Participant mean excludes outlier values.

FIGURES 23-24. Reproducibility of Results by Different Methods - Glutarylcarnitine (C5DC) and Hexanoylcarnitine (C6)

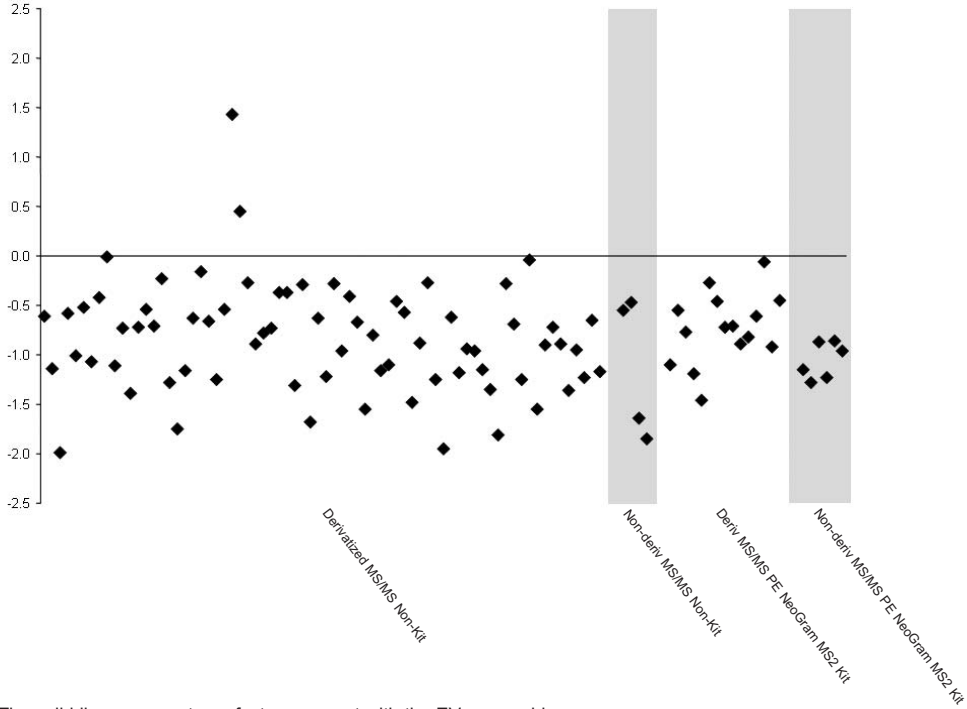
	Quarter 2
Specimen 1	
CDC Assayed	0.04
Participant Mean	0.04
Specimen 2	
CDC Assayed	0.04
Participant Mean	0.04
Specimen 3	
CDC Assayed	0.09
Participant Mean	0.06
Specimen 4	
CDC Assayed	0.10
Participant Mean	0.07
Specimen 5	
CDC Assayed	0.86
Participant Mean	0.60
Participant Bias[3]	-0.26

Figure 23. Bias Plot of Glutarylcarnitine (C5DC) Values by Method
Quarter 2, Specimen 5
Assayed Value (AV)[4] 0.86 µmol/L whole blood



	Quarter 2
Specimen 1	
Enriched	0
CDC Assayed	0.04
Participant Mean	0.06
Specimen 2	
Enriched	0
CDC Assayed	0.03
Participant Mean	0.06
Specimen 3	
Enriched	3.00
CDC Assayed	2.50
Participant Mean	2.17
CDC Bias[2]	-0.55
Participant Bias[3]	-0.88
Specimen 4	
Enriched	0
CDC Assayed	0.11
Participant Mean	0.12
Specimen 5	
Enriched	2.50
CDC Assayed	2.58
Participant Mean	2.35

Figure 24. Bias Plot of Hexanoylcarnitine (C6) Values by Method
Quarter 2, Specimen 3
Expected Value (EV)[1] 3.05 µmol/L whole blood

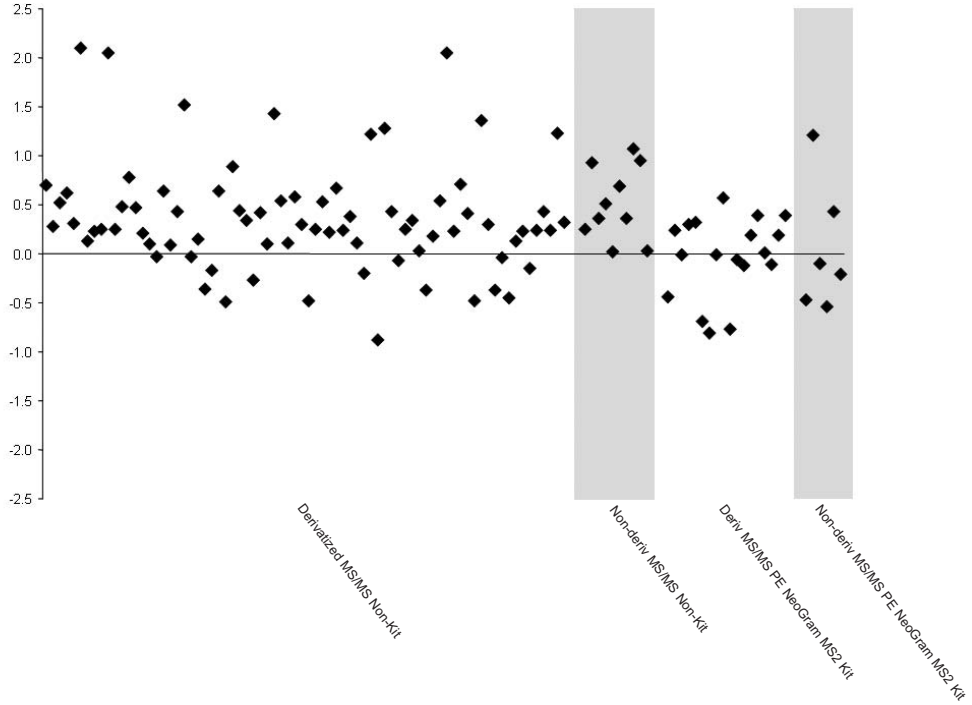


[1]EV is the sum of the endogenous and enrichment values. The solid line represents perfect agreement with the EV or zero bias.
[2]± CDC bias is the CDC assayed value minus EV.
[3]± Participant bias is the Participant mean assayed value minus EV. The Participant mean excludes outlier values.
[4]AV is the CDC assayed value. The solid line represents perfect agreement with the AV or zero bias.

FIGURES 25-26. Reproducibility of Results by Different Methods - Octanoylcarnitine (C8) and Decanoylcarnitine (C10)

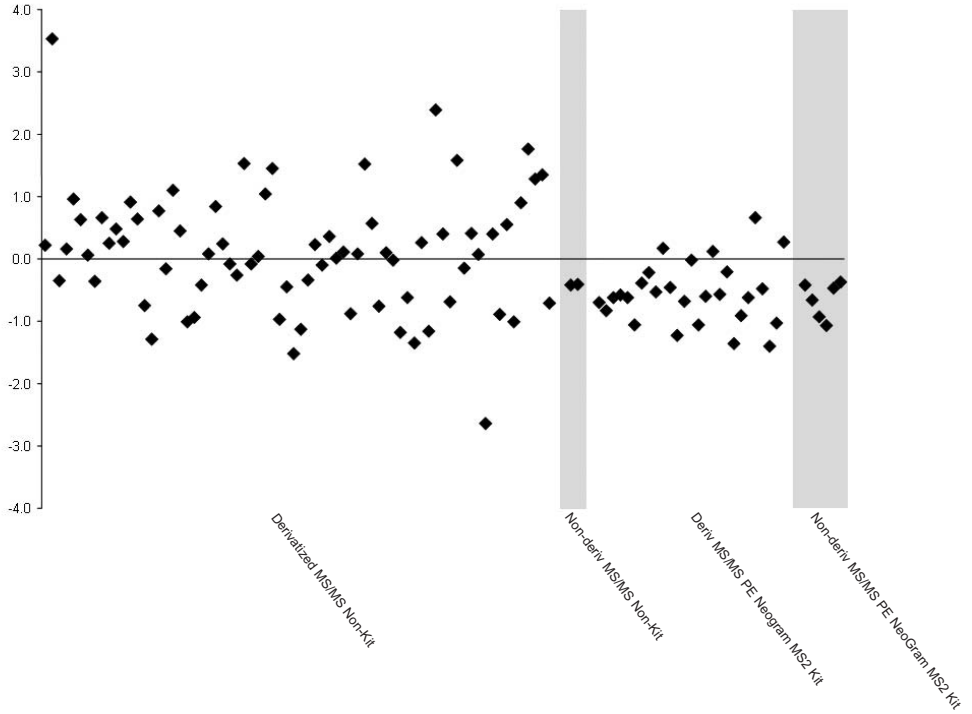
	Quarter 2
Specimen 1	
Enriched	0
CDC Assayed	0.07
Participant Mean	0.08
Specimen 2	
Enriched	0
CDC Assayed	0.06
Participant Mean	0.08
Specimen 3	
Enriched	15.00
CDC Assayed	15.65
Participant Mean	13.46
Specimen 4	
Enriched	0
CDC Assayed	0.21
Participant Mean	0.20
Specimen 5	
Enriched	2.50
CDC Assayed	3.17
Participant Mean	2.81
CDC Bias[2]	0.6
Participant Bias[3]	0.24

Figure 25. Bias Plot of Octanoylcarnitine (C8) Values by Method
Quarter 2, Specimen 5
Expected Value (EV)[1] 2.57 µmol/L whole blood



	Quarter 3
Specimen 1	
Enriched	3.00
CDC Assayed	3.19
Participant Mean	3.08
CDC Bias[2]	-0.03
Participant Bias[3]	-0.14
Specimen 2	
Enriched	0
CDC Assayed	0.09
Participant Mean	0.10
Specimen 3	
Enriched	0
CDC Assayed	0.20
Participant Mean	0.22
Specimen 4	
Enriched	0
CDC Assayed	0.21
Participant Mean	0.23
Specimen 5	
Enriched	0
CDC Assayed	0.22
Participant Mean	0.22

Figure 26. Bias Plot of Decanoylcarnitine (C10) Values by Method
Quarter 3, Specimen 1
Expected Value (EV)[1] 3.22 µmol/L whole blood

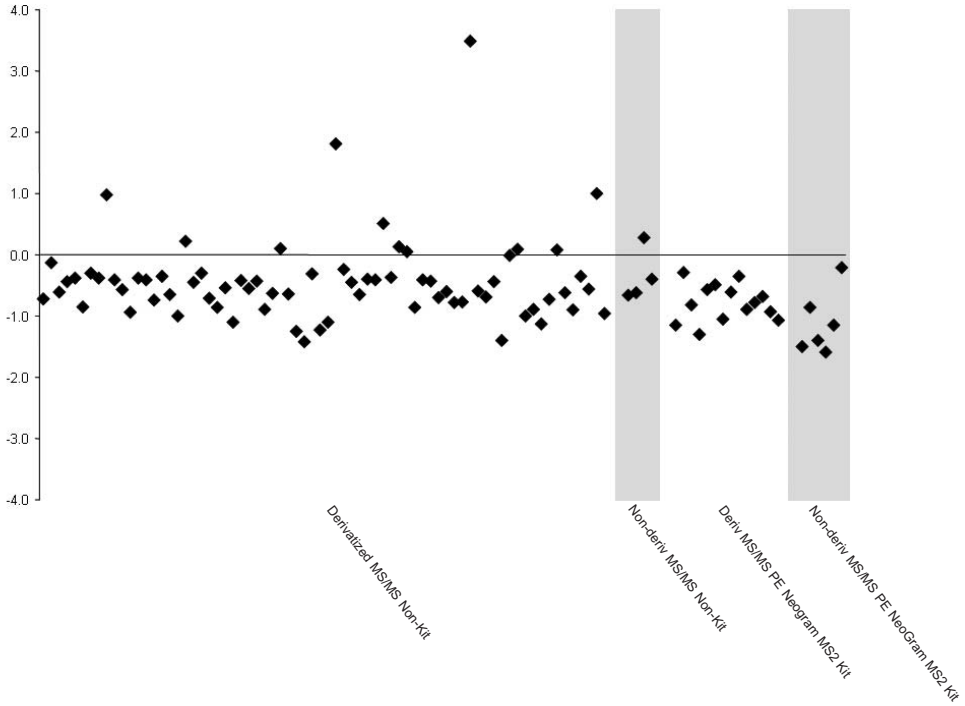


[1]EV is the sum of the endogenous and enrichment values. The solid line represents perfect agreement with the EV or zero bias.
[2]± CDC bias is the CDC assayed value minus EV.
[3]± Participant bias is the Participant mean assayed value minus EV. The Participant mean excludes outlier values.

FIGURES 27-28. Reproducibility of Results by Different Methods - Myristoylcarnitine (C14) and Palmitoylcarnitine (C16)

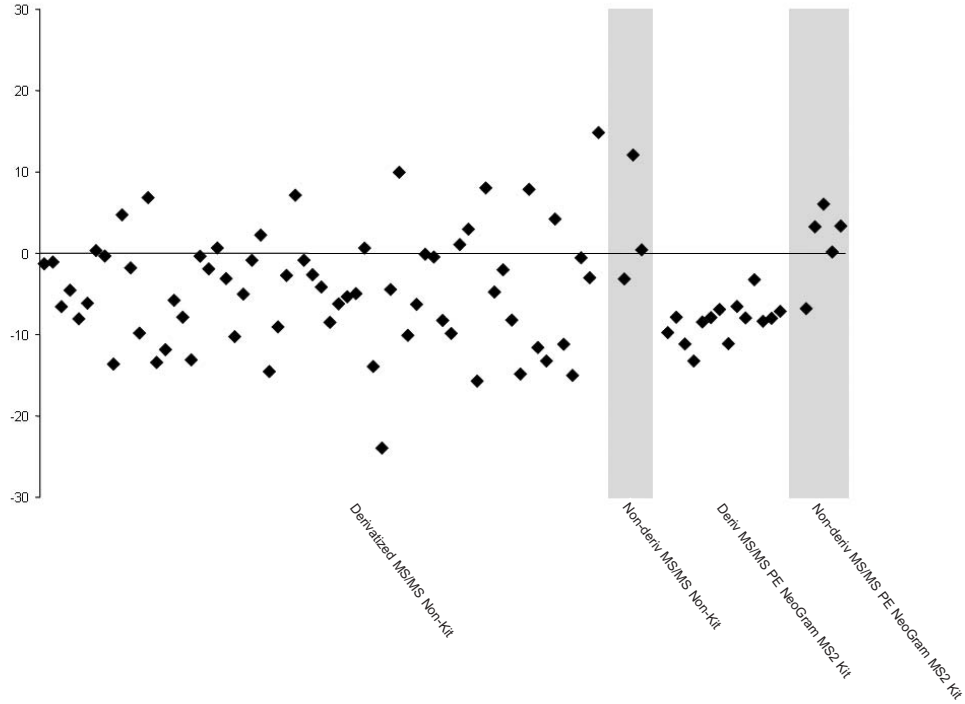
	Quarter 2
Specimen 1	
Enriched	0
CDC Assayed	0.15
Participant Mean	0.14
Specimen 2	
Enriched	0
CDC Assayed	0.16
Participant Mean	0.14
Specimen 3	
Enriched	0
CDC Assayed	0.12
Participant Mean	0.12
Specimen 4	
Enriched	2.50
CDC Assayed	2.28
Participant Mean	1.98
CDC Bias[2]	-0.32
Participant Bias[3]	-0.62
Specimen 5	
Enriched	3.00
CDC Assayed	3.83
Participant Mean	3.04

Figure 27. Bias Plot of Myristoylcarnitine (C14) Values by Method
Quarter 2, Specimen 4
Expected Value (EV)[1] 2.60 µmol/L whole blood



	Quarter 1
Specimen 1	
Enriched	32.00
CDC Assayed	29.16
Participant Mean	28.72
CDC Bias[2]	-4.09
Participant Bias[3]	-4.53
Specimen 2	
Enriched	0
CDC Assayed	0.93
Participant Mean	1.08
Specimen 3	
Enriched	0
CDC Assayed	0.55
Participant Mean	0.58
Specimen 4	
Enriched	0
CDC Assayed	0.59
Participant Mean	0.57
Specimen 5	
Enriched	0
CDC Assayed	0.97
Participant Mean	0.97

Figure 28. Bias Plot of Palmitoylcarnitine (C16) Values by Method
Quarter 1, Specimen 1
Expected Value (EV)[1] 33.25 µmol/L whole blood



[1]EV is the sum of the endogenous and enrichment values. The solid line represents perfect agreement with the EV or zero bias.
[2]± CDC bias is the CDC assayed value minus EV.
[3]± Participant bias is the Participant mean assayed value minus EV. The Participant mean excludes outlier values.

FIGURE 29. EXPLANATION OF NSQAP GRADING ALGORITHM

Part 1.
The expected clinical assessment (EA) for a proficiency testing (PT) specimen is determined by comparing the expected value (EV), which is the sum of endogenous and enrichment values, with the CDC cutoff. The production of a PT specimen is designed so that the 99% confidence interval (CI) for the expected value (EV) of a positive specimen falls above the CDC cutoff, and the 99% CI for the expected value (EV) of a negative specimen falls below the CDC cutoff. Specimens that do not meet this 99% CI criterion are declared not-gradable/not-evaluated (NE).

Part 2.
When your reported clinical assessment (RA) differs from the expected clinical assessment (EA), the expected value (EV) is compared with the cutoff that you provide. This determines what your laboratory expected clinical assessment (LA) should be. If the expected clinical assessment (EA) and the laboratory expected clinical assessment (LA) are the same, but different from your reported clinical assessment (RA), your grade is either false-negative or false-positive. If the expected clinical assessment (EA) and the laboratory expected clinical assessment (LA) are not the same, your reported clinical assessment (RA) will not be graded as incorrect because of a significant difference between the CDC cutoff and your cutoff (see examples below). If you do not provide a cutoff, your laboratory expected clinical assessment (LA) cannot be determined; and your grade will be based on the CDC cutoff.

Part 3.
NSQAP's determination of a final clinical assessment for a specimen is based on the Clinical Laboratory Improvement Amendments (CLIA) regulations (http://www.phppo.cdc.gov/clia/regs/subpart_i.aspx#493.929), whereby the PT provider "must compare the laboratory's response for each analyte with the response that reflects agreement of either 80% of ten or more referee laboratories or 80% or more of all participating laboratories." A NSQAP gradable specimen must have 80% or more agreement among domestic laboratories. A specimen with less than 80% agreement is not-gradable/not-evaluated (NE).

Examples of Grading Scenarios

Analyte	CDC Cutoff	Expected Value (EV)	Lab Cutoff	Assessment: (EA) EV/CDC cutoff	Assessment: (LA) EV/Lab cutoff	Assessment: (RA) Lab reported	Lab Grade
TSH	25	13	30	Neg	Neg	Pos	FP
TSH	25	13	10	Neg	Pos	Pos	CD
Leu	4.1	6.7	4.5	Pos	Pos	Neg	FN
Leu	4.1	6.7	8.0	Pos	Neg	Neg	CD

FN = False negative
FP = False positive
CD = Cutoff Difference - clinical assessment is not judged as incorrect

TSH = Thyroid-stimulating Hormone
Leu = Leucine

Note that the grade is based on the reported clinical assessment, not on the reported value. Overall Statistics, which are generated from all participants' data, and Mean Reported Concentrations by method are provided on this Web site for analytical reference only.

TABLE 3. 2005 Summary of Proficiency Testing Errors by Domestic and Foreign Laboratories

Domestic	Positive Specimens Assayed (N)	False-Negative Errors (%)	Negative Specimens Assayed (N)	False-Positive Errors (%)
Phenylketonuria	252	0.8	1008	0.4
Maple Syrup Urine Disease (Leu)	145	0	580	0
Homocystinuria	143	1.4	572	0.2
Tyrosinemia	135	0	540	0
Maple Syrup Urine Disease (Val)	113	0	452	1.8
Citrullinemia	122	0	488	0
C3 Screen	164	0	506	0.2
C4 Screen	229	1.7	411	1.2
C5 Screen	203	0	467	0.2
C5DC Screen	132	0	528	0.6
C6 Screen	156	0.6	484	0.2
C8 Screen	184	1.1	566	0.2
C10 Screen	188	1.1	462	0.9
C14 Screen	148	0	457	0
C16 Screen	164	0.6	506	0
Hypothyroidism	338	2.4	527	0.2
Congenital Adrenal Hyperplasia	368	2.2	352	0
Galactosemia	181	0.6	269	0
Biotinidase Deficiency	106	0	424	0
GALT Deficiency	184	0	736	0.1
Cystic Fibrosis (IRT)	77	2.6	108	0

Foreign	Positive Specimens Assayed (N)	False-Negative Errors (%)	Negative Specimens Assayed (N)	False-Positive Errors (%)
Phenylketonuria	573	0.9	2292	2.4
Maple Syrup Urine Disease (Leu)	279	0	996	1.2
Homocystinuria	260	1.5	1040	0.9
Tyrosinemia	290	1.4	1160	0.2
Maple Syrup Urine Disease (Val)	232	0.9	928	1.1
Citrullinemia	236	0.4	944	1.0
C3 Screen	333	1.2	992	0.6
C4 Screen	460	0.7	787	1.4
C5 Screen	401	0.7	929	0.4
C5DC Screen	256	1.6	1028	0.2
C6 Screen	323	0.9	967	0.6
C8 Screen	355	0.3	1060	1.5
C10 Screen	394	1.0	906	1.9
C14 Screen	322	0.9	963	0.2
C16 Screen	333	1.2	992	0.3
Hypothyroidism	957	0.8	1523	1.6
Congenital Adrenal Hyperplasia	554	1.4	536	0.7
Galactosemia	371	1.6	569	0.2
Biotinidase Deficiency	138	1.4	552	0.7
GALT Deficiency	113	1.8	452	2.0
Cystic Fibrosis (IRT)	265	0.4	363	0.6

nately negative bias with the expected value. For Cit (Figure 18), the predominately used method showed a negative bias and two methods showed a reasonable scatter about the expected value. For IRT (Figure 19), the reported results agreed reasonably with the CDC assayed value for most methods, whereas two methods showed a large negative bias.

Since last year, the 17-OHP mean cutoff for domestic labs increased from 48.5 to 62.2; and for foreign labs, it decreased from 30.7 to 28.7.

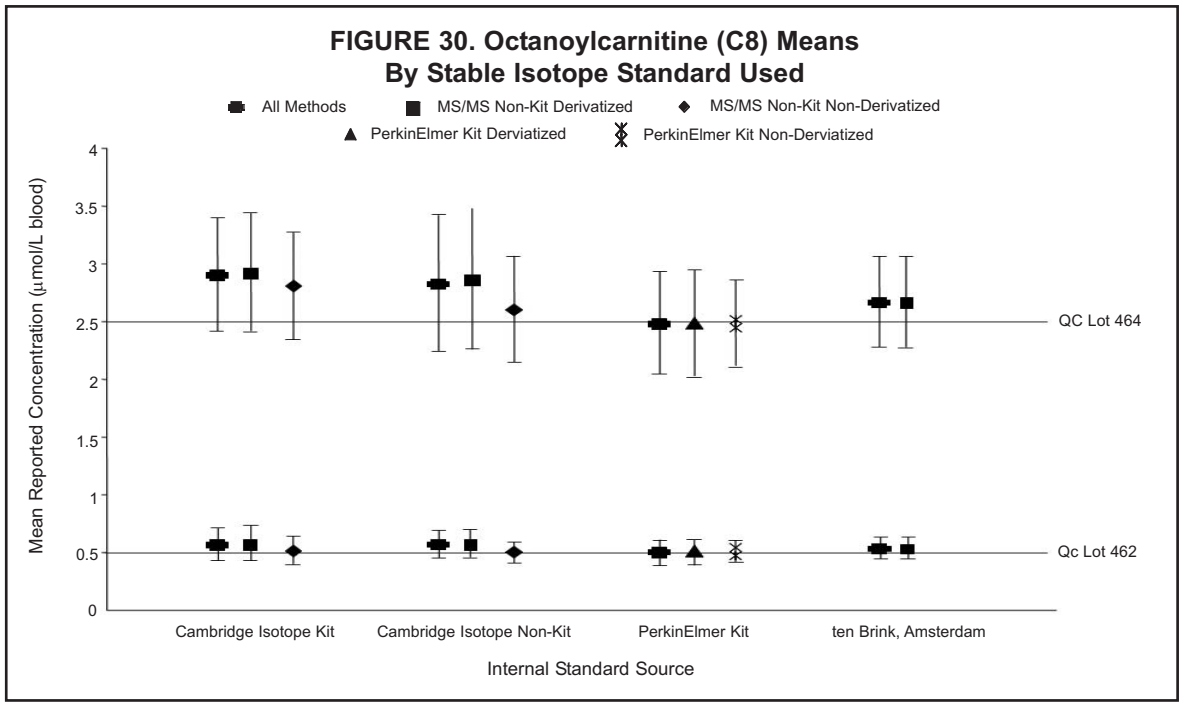
Representative bias plots are shown for all acylcarnitines in the PT challenges. Reported values for C3 and C4 (Figures 20 and 21) showed reasonable scatter about the expected value while the reported values for C5 (Figure 22) and C10 (Figure 26) showed a consistent negative bias with the expected values with a reasonably consistent scatter among the users and methods. The reported values for C5DC (Figure 23) showed a low scatter of values with a slightly negative bias except for two of the less frequently used methods; however, one method showed a high scatter of values with a large positive bias for some laboratories. The reported values for C6 (Figure 24) showed a consistently negative bias with a relatively tight clustering of values. For C8 (Figure 25), a slight positive bias was observed with most laboratories reporting values close to the expected value. For C14 (Figure 27), the reported values showed a tight scatter with a slightly negative bias among all laboratories and methods. One method for C16 (Figure 28) showed a tight cluster of values, but all user laboratories showed a strong negative bias.

Table 3 shows the proficiency testing errors reported by disorder in 2005 for all qualitative assessments by domestic laboratories and by foreign laboratories. We applied the laboratory-reported specific cutoff values to our grading algorithm for clinical assessments (Figure 29). Presumptive clinical classifications (qualitative assessments) of some specimens may differ by participant because of specific clinical assessment practices. If participants provided us with their cutoff values, we applied these cutoffs in our final appraisal of the error judgment. We based the rates for false-positive misclassifications on the number of distributed negative specimens and the rates for false-negative misclassifications on the number of positive specimens. False-positive misclassifications, which are a cost-benefit issue and a credibility factor for follow-up programs, should be monitored and kept as low as possible. Many of the misclassifications were in the false-positive category, with false-positive rates ranging from 0% to 2.4%. For domestic laboratories, the rate was 0.6% or lower for 18 of 21 biomarkers or disorders; and for foreign laboratories, the rate was 0.9% or lower for 12 of 21 biomarkers or disorders. Screening programs are designed to avoid false-negative reports; this precautionary design, however, contributes to false-positive reports and may cause many of the false-positive misclassifications. The false-negative rate, expected to be zero, ranged from 0% to 2.6%. False-negative classifications were reported for all biomarkers or disorders except for maple syrup urine disease (Leu). For 10 biomarkers or disorders, no false-negative errors were reported for the domestic laboratories. A few of our PT specimens fell close to the decision level for classifications and thus rigorously tested the ability of laboratories to make the expected cutoff decision. Most specimens near the mean cutoff value are distributed as not-evaluated specimens and are not included in Table 3. Participants' data for these specimens are used to examine the relative analytical performance of the assays.

Table 4 shows the performance errors for hemoglobinopathies. The percentage of errors for qualitative assessments for sickle cell disease and other hemoglobinopathies ranged from 0.7% to 2.4% for the error categories, with 51 of 64 laboratories correctly classifying all specimens. The classification errors were essentially the same for phenotype and clinical assessments within the domestic and foreign laboratory groups. Table 5 shows the phenotype challenges that were dis-

Most Common Reasons for False-Negative Errors Reported by Laboratories

Low quantitative value
Transcription error
Analytic testing error



tributed in 2005 for hemoglobinopathies. Table 6 shows the CF genotype challenges in 2005, which were combined with varying levels of IRT to yield a total challenge of the test algorithm for presumptive positive classifications.

Low quantitative value was the most frequent explanation among the most common reasons for false-negative errors reported by domestic participants identified upon follow-up by NSQAP.

QUALITY CONTROL

For QC shipments of T_4, TSH, 17-OHP, Gal, amino acids (Phe, Leu, Met, Tyr, Val, Cit), and acylcarnitines (C2, C3, C4, C5, C5DC, C6, C8, C10, C14, C16), each lot within a set contained a different analyte concentration. To ensure that a laboratory received representative sheets of the production batch, we used a randomizing system to select the set of sheets from the production batch for each laboratory. The QC materials were distributed semiannually and included the DBS sheets, instructions for storage and analysis, and data-report forms. Data from five analytic runs of each lot and shipment were compiled in the midyear and annual summary reports distributed to each participant. Intervals between runs were not the same for all laboratories because each participant's reported data cover a different time span.

Figure 30 shows means and standard deviations (SD) by stable isotope internal standard used for testing two C8 QC lots by four methods. The internal standards gave consistent results across both QC lots with a small difference for derivatized vs. nonderivatized methods.

The reported QC data are summarized in Tables 7a–7t, which show the analyte by series of QC lots, the number of measurements (N), the mean values, and the within laboratory and total SDs by kit or analytic method. In addition, we used a weighted linear regression analysis to examine the comparability by method of reported versus enriched concentrations. Linear regressions (Y-intercept and slope) were calculated by method for all analytic values within an analyte QC series. Values outside the 99% CI (outliers) were excluded from the calculations.

Tables 7a–7t provide data about method-related differences in analytic recoveries and method bias. Because we prepared each QC lot series from one batch of hematocrit-adjusted, nonenriched blood, the endogenous concentration was the same for all specimens in a lot series. We calculated the within-laboratory SD component of the total SD and used the reported QC data from multiple analytic runs for regression analyses. We calculated the Y-intercept and slope in each table using all analyte concentrations within a lot series (e.g., lots 511, 512, and

TABLE 4. Summary of Proficiency Testing Errors for Hemoglobinopathies by Domestic and Foreign Laboratories

Hemoglobinopathies	Domestic	Foreign
Specimens assayed	960	205
Phenotype errors	0.6%	2.0%
Clinical assessment errors	0.7%	2.4%

Overall, there were 10 phenotype errors in 2005, one SC, one FC, one FAC, two FA, two FAS, and three FAJ.

TABLE 5. Hemoglobin Phenotype Challenges Distributed in 2005

Phenotype	N
FA	5
FS	3
FAC	4
FAS	5
FSC	3

513). Because only three or four concentrations of QC materials are available for each analyte, a bias error in any one pool can markedly influence the slope and intercept. The Y-intercept provides one measure of the endogenous concentration level for an analyte. For Phe, Leu, Met, Tyr, Val, and Cit, participants also measured the endogenous concentrations by analyzing the nonenriched QC lots; the Y-intercepts and measured endogenous levels for these analytes were similar for most methods. Ideally, the slope should be 1.0, and most slopes were close to this value; however, the range was 0.25 to 2.50 because of a few methods and analytes. One T_4 method (In house) had a slope of 0.6. Two TSH methods had slopes higher than expected, with values of 1.3 (lots 411–413) and 1.4 (lots 411–413 and 511–513). One Gal method yielded a slope of 1.4 (lots 421–424), and one method had a slope of 1.5 (lots 425–428 and 521–524). Two Phe methods had slopes of 1.3 for lots 425–428, and the same method had slopes of 1.4 for lots 521–524. All slopes for lots 421–424 were within the expected range for the Phe methods. Three Leu methods yielded slopes of 1.3 for lots 421–424 and two of the same methods for lots 425–428, and one Leu method had a slope of 1.6 for lots 421–424 and 1.5 for lots 425–428. One Leu method had a slope of 0.6 for lots 521–524, and one Met method had a slope of 0.7 (lots 421–424 and 521–524). For Tyr, one method had a slope of 0.6 for lots 425–428, and two Val methods had low slope values of 0.6 and 0.7 (lots 421–424, lots 425–428, and lots 521–524). Two Cit methods had low slope values of 0.6 and 0.7 (lots 421–424) and one method a high slope of 2.5. The MS/MS derivatized kit gave the best slope of 1.0 and good recoveries relative to the expected values.

For the acylcarnitines, many methods yielded poor average slope measurements. For C2, two methods gave slopes of 0.46 and 0.71 for lots 461–464. The base serum pool (zero enrichment) for lot 461 had high values before enrichment for C2. This higher base pool value along with the range of enriched values may have contributed to these low slope values. Slope values for C3, C4, and C5 fell within the acceptable limits. For C5DC, the slopes were 0.25 and 1.85 (lots 461–464) and these same methods yielded slopes of 0.10 and 1.82 for lots 561–564. Two of the four methods for C5DC gave slopes within accepted limits and good recoveries relative to the expected values. Several different internal standards were used by participants to calculate the C5DC values by both kit and non-kit methods. Laboratories in each group indicated using derivatized and non-derivatized methods. The data were not sorted by type of internal standard. These differences could have contributed to the problems shown in Table 7o. The slopes for C6 and C8 were within accepted limits. For C10, two methods yielded slopes of 1.26 and 1.23 for lots 461–464, one of these same methods yielded a slope of 1.24 for lots 561–564, and for the other, a slope of 1.09. One C14 method produced a slope of 0.66 for lots 561–564, but this method was within accepted limits for lots 461–464. C16 was within accepted slope limits for all methods and demonstrated good recoveries relative to the expected values.

Slope deviations may be related to analytic (dose-response) ranges for calibration curves or to poor recoveries for one or more specimens in a three- or four-specimen QC set. Because the endogenous concentration was the same for all QC lots within a series, it should not affect the slope of the regression line among methods. Generally, slope values substantially different from 1.0 indicate a method has an analytic bias.

TABLE 6. Genotype Analysis of IRT Positive Cystic Fibrosis Specimens in 2005

Genotype	Number of Results	Correct Results (%)
ΔF508/ΔF508	100	96 (96%)
Wild Type/Wild Type	58	58 (100%)

More than 12 methods were used by participants including Roche Linear Array (ASO), Tepnel Diagnostics Elucigene (ARMS), Innogenetics Inno-LiPA, Tm Bioscience Tag-It, Abbott Diagnostics Oligonucleotide Ligation Assay, In-house PCR.

REFERENCES

1. Hannon WH, Baily CM, Bartoshesky LE, Davin B, Hoffman GL, King PP, et al. Blood collection on filter paper for newborn screening programs. Fourth edition, approved standard. Wayne (PA): NCCLS; 2003 NCCLS Document LA4-A4.

TABLE 7a. 2005 Quality Control Data
Summaries of Statistical Analyses

THYROXINE (μg T_4/dL serum)

Method	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 301 - Enriched 2 μg/dL serum						
Diagnostic Products	10	2.3	0.3	0.3	0.3	1.0
MP Biomedicals (ICN) RIA	40	2.0	0.5	0.5	0.2	0.9
Neo-Genesis (Neomet) Accuwell	97	1.5	0.6	0.7	-0.2	1.0
Delfia	218	1.6	0.3	0.5	-0.1	0.9
AutoDelfia	636	1.7	0.4	0.6	-0.2	0.9
In House	10	2.5	0.6	0.6	1.5	0.6
Other	50	2.2	0.6	0.6	0.2	1.0
Lot 302 - Enriched 7 μg/dL serum						
Diagnostic Products	10	7.0	0.8	0.8	0.3	1.0
MP Biomedicals (ICN) RIA	70	6.7	1.0	1.3	0.2	0.9
Neo-Genesis (Neomet) Accuwell	86	6.8	1.2	1.3	-0.2	1.0
Delfia	227	6.1	0.7	0.9	-0.1	0.9
AutoDelfia	624	6.3	0.8	1.4	-0.2	0.9
In House	10	5.9	0.3	0.3	1.5	0.6
Other	50	7.2	0.8	0.8	0.2	1.0
Lot 303 - Enriched 11 μg/dL serum						
Diagnostic Products	10	11.0	1.3	1.3	0.3	1.0
MP Biomedicals (ICN) RIA	69	10.2	1.2	2.1	0.2	0.9
Neo-Genesis (Neomet) Accuwell	98	10.1	2.0	2.5	-0.2	1.0
Delfia	228	9.3	1.0	1.2	-0.1	0.9
AutoDelfia	623	10.0	1.3	2.4	-0.2	0.9
In House	10	7.6	0.6	0.6	1.5	0.6
Other	50	11.3	1.6	1.9	0.2	1.0

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

TABLE 7b. 2005 Quality Control Data
Summaries of Statistical Analyses

THYROID-STIMULATING HORMONE (μIU TSH/mL serum)

Method	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 411 - Enriched 25 μIU/mL serum						
Diagnostic Products	49	33.1	3.2	3.4	0.6	1.3
Neo-Genesis (Neomet) Accuwell	69	25.7	3.9	4.9	-2.3	1.1
MP Biomedicals (ICN) IRMA	60	31.2	3.0	3.4	3.3	1.1
MP Biomedicals (ICN) ELISA	60	23.9	2.1	3.4	-1.1	1.0
Delfia	994	27.2	3.5	4.4	-1.7	1.2
AutoDelfia	1304	27.2	2.7	3.7	-1.6	1.2
Ani Labsystems (Thermo)	81	25.3	2.3	3.4	1.6	1.0
Bio-Rad Quantase	232	30.8	4.6	6.0	-4.4	1.4
TecnoSuma UMELISA	37	31.0	3.2	3.7	2.5	1.2
Bioclone ELISA	32	32.6	4.2	7.5	2.9	1.3
DiaSorin	154	26.7	3.6	4.6	0.0	1.1
In House	126	28.6	3.5	5.7	3.3	1.0
Other	323	27.4	2.8	7.5	-0.5	1.2
Lot 412 - Enriched 40 μIU/mL serum						
Diagnostic Products	49	50.6	3.4	4.0	0.6	1.3
Neo-Genesis (Neomet) Accuwell	69	41.6	5.3	6.8	-2.3	1.1
MP Biomedicals (ICN) IRMA	59	47.6	4.1	4.7	3.3	1.1
MP Biomedicals (ICN) ELISA	58	38.9	3.0	4.1	-1.1	1.0
Delfia	999	44.0	5.5	6.7	-1.7	1.2
AutoDelfia	1293	44.9	4.2	5.2	-1.6	1.2
Ani Labsystems (Thermo)	83	42.4	3.9	4.9	1.6	1.0
Bio-Rad Quantase	213	51.8	7.5	9.5	-4.4	1.4
TecnoSuma UMELISA	40	49.0	5.9	7.3	2.5	1.2
Bioclone ELISA	34	56.3	9.0	15.4	2.9	1.3
DiaSorin	150	46.5	5.5	6.5	0.0	1.1
In House	129	45.7	7.3	9.6	3.3	1.0
Other	330	46.8	4.8	12.4	-0.5	1.2
Lot 413 - Enriched 80 μIU/mL serum						
Diagnostic Products	50	102.7	6.6	13.1	0.6	1.3
Neo-Genesis (Neomet) Accuwell	74	86.4	11.3	13.3	-2.3	1.1
MP Biomedicals (ICN) IRMA	60	92.2	8.6	9.2	3.3	1.1
MP Biomedicals (ICN) ELISA	59	78.9	5.0	8.0	-1.1	1.0
Delfia	963	90.4	9.8	12.6	-1.7	1.2
AutoDelfia	1291	90.9	8.2	9.9	-1.6	1.2
Ani Labsystems (Thermo)	85	80.2	7.1	12.4	1.6	1.0
Bio-Rad Quantase	214	108.1	13.0	17.6	-4.4	1.4
TecnoSuma UMELISA	38	94.7	11.1	16.6	2.5	1.2
Bioclone ELISA	32	103.6	17.5	27.0	2.9	1.3
DiaSorin	149	89.1	10.4	12.2	0.0	1.1
In House	120	86.0	10.0	21.2	3.3	1.0
Other	326	91.3	8.8	22.1	-0.5	1.2

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

THYROID-STIMULATING HORMONE (μIU/mL serum)

- continued -

Method	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 511 - Enriched 25 μIU/mL serum						
Diagnostic Products	30	29.3	3.1	10.6	5.2	1.0
Neo-Genesis (Neomet) Accuwell	40	29.1	4.8	6.2	-1.6	1.2
MP Biomedicals (ICN) IRMA	20	26.8	1.9	9.6	5.3	0.9
MP Biomedicals (ICN) ELISA	19	20.8	2.0	2.4	-1.0	0.9
Delfia	522	27.7	3.1	4.0	0.6	1.1
AutoDelfia	724	28.2	2.5	3.2	1.0	1.1
Ani Labsystems (Thermo)	69	27.8	2.9	7.0	3.1	1.0
Bio-Rad Quantase	130	33.7	4.0	7.2	-3.8	1.4
TecnoSuma UMELISA	29	33.3	2.9	5.9	1.3	1.2
Bioclone ELISA	20	39.0	4.2	5.8	4.2	1.4
DiaSorin	70	29.3	3.5	4.4	1.1	1.1
In House	88	29.9	4.0	4.8	3.8	1.0
Other	162	28.9	2.7	9.5	1.8	1.1
Lot 512 - Enriched 40 μIU/mL serum						
Diagnostic Products	30	43.8	3.2	14.8	5.2	1.0
Neo-Genesis (Neomet) Accuwell	40	42.4	6.8	7.8	-1.6	1.2
MP Biomedicals (ICN) IRMA	20	45.6	2.9	7.1	5.3	0.9
MP Biomedicals (ICN) ELISA	20	34.0	5.2	5.2	-1.0	0.9
Delfia	528	43.6	4.4	5.3	0.6	1.1
AutoDelfia	719	43.2	3.7	4.5	1.0	1.1
Ani Labsystems (Thermo)	67	44.1	3.1	9.3	3.1	1.0
Bio-Rad Quantase	130	51.0	5.0	7.4	-3.8	1.4
TecnoSuma UMELISA	28	49.7	5.7	9.6	1.3	1.2
Bioclone ELISA	17	61.4	3.7	6.3	4.2	1.4
DiaSorin	70	47.2	4.4	4.9	1.1	1.1
In House	88	43.6	4.2	5.5	3.8	1.0
Other	165	46.5	4.7	14.8	1.8	1.1
Lot 513 - Enriched 80 μIU/mL serum						
Diagnostic Products	30	82.2	4.6	29.2	5.2	1.0
Neo-Genesis (Neomet) Accuwell	32	91.8	9.2	9.2	-1.6	1.2
MP Biomedicals (ICN) IRMA	20	79.7	4.1	14.4	5.3	0.9
MP Biomedicals (ICN) ELISA	20	68.8	13.2	13.2	-1.0	0.9
Delfia	520	87.0	8.2	10.2	0.6	1.1
AutoDelfia	724	86.8	7.7	10.5	1.0	1.1
Ani Labsystems (Thermo)	66	83.6	6.7	14.3	3.1	1.0
Bio-Rad Quantase	124	111.3	10.7	15.9	-3.8	1.4
TecnoSuma UMELISA	29	101.0	9.1	27.2	1.3	1.2
Bioclone ELISA	20	116.9	12.3	19.4	4.2	1.4
DiaSorin	68	92.3	9.4	11.2	1.1	1.1
In House	88	85.3	9.9	17.4	3.8	1.0
Other	162	89.9	8.6	27.4	1.8	1.1

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

TABLE 7c. 2005 Quality Control Data
Summaries of Statistical Analyses

17 α-HYDROXYPROGESTERONE (ng 17-OHP/mL serum)

Method	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 351 - Enriched 25 ng/mL serum						
MP Biomedicals (ICN) RIA	10	25.6	2.2	2.2	-0.8	1.0
Neo-Genesis (Neomet) Accuwell	19	26.8	3.1	3.1	1.5	1.0
Delfia	140	27.1	2.7	4.0	-2.2	1.1
AutoDelfia	373	28.2	2.5	3.2	0.2	1.1
Bio-Rad Quantase	20	25.9	9.8	9.8	4.8	0.8
Bayer Medical EIA	10	29.0	2.5	2.5	-0.5	1.1
In house	10	29.9	4.2	4.2	4.5	0.9
Other	20	28.2	2.5	4.3	1.5	1.1
Lot 352 - Enriched 50 ng/mL serum						
MP Biomedicals (ICN) RIA	10	44.8	4.7	4.7	-0.8	1.0
Neo-Genesis (Neomet) Accuwell	20	48.5	6.3	6.5	1.5	1.0
Delfia	139	51.3	4.6	7.4	-2.2	1.1
AutoDelfia	372	53.1	4.2	5.4	0.2	1.1
Bio-Rad Quantase	18	44.6	5.7	7.9	4.8	0.8
Bayer Medical EIA	10	47.4	7.0	7.0	-0.5	1.1
In house	10	46.2	6.1	6.1	4.5	0.9
Other	20	53.6	4.2	10.1	1.5	1.1
Lot 353 - Enriched 100 ng/mL serum						
MP Biomedicals (ICN) RIA	10	97.6	16.6	16.6	-0.8	1.0
Neo-Genesis (Neomet) Accuwell	19	98.9	15.7	17.4	1.5	1.0
Delfia	144	110.0	10.7	18.1	-2.2	1.1
AutoDelfia	373	109.1	10.7	13.0	0.2	1.1
Bio-Rad Quantase	19	86.8	30.4	30.4	4.8	0.8
Bayer Medical EIA	10	106.5	10.9	10.9	-0.5	1.1
In house	10	96.9	9.0	9.0	4.5	0.9
Other	20	107.1	10.6	30.4	1.5	1.1

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

17 α-HYDROXYPROGESTERONE (ng 17-OHP/mL serum)
- continued -

Method	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 451 - Enriched 25 ng/mL serum						
MP Biomedicals (ICN) RIA	39	26.2	3.2	3.2	1.5	1.0
Neo-Genesis (Neomet) Accuwell	48	28.6	5.2	5.5	5.5	1.0
Delfia	338	27.4	3.3	4.1	-0.3	1.1
AutoDelfia	823	30.0	3.4	4.1	-0.5	1.2
Bio-Rad Quantase	58	25.2	5.9	6.1	-2.9	1.1
Bayer Medical EIA	20	28.8	3.1	3.1	0.9	1.1
In house	29	24.0	3.9	6.1	3.3	0.8
Other	68	27.3	4.0	4.6	2.5	1.0
Lot 452 - Enriched 50 ng/mL serum						
MP Biomedicals (ICN) RIA	40	54.1	6.1	6.1	1.5	1.0
Neo-Genesis (Neomet) Accuwell	48	58.4	6.7	6.7	5.5	1.0
Delfia	338	54.6	6.0	7.3	-0.3	1.1
AutoDelfia	819	59.3	6.3	7.7	-0.5	1.2
Bio-Rad Quantase	60	47.8	6.1	8.2	-2.9	1.1
Bayer Medical EIA	20	54.8	7.4	7.4	0.9	1.1
In house	37	45.2	5.4	9.3	3.3	0.8
Other	69	52.9	8.5	12.7	2.5	1.0
Lot 453 - Enriched 100 ng/mL serum						
MP Biomedicals (ICN) RIA	40	103.6	8.3	9.0	1.5	1.0
Neo-Genesis (Neomet) Accuwell	49	104.7	18.9	18.9	5.5	1.0
Delfia	330	110.0	12.5	18.6	-0.3	1.1
AutoDelfia	830	120.2	12.1	15.0	-0.5	1.2
Bio-Rad Quantase	58	103.8	23.6	24.7	-2.9	1.1
Bayer Medical EIA	20	110.5	12.6	12.6	0.9	1.1
In house	38	86.6	11.4	18.4	3.3	0.8
Other	69	102.5	19.4	25.8	2.5	1.0

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

TABLE 7d. 2005 Quality Control Data
Summaries of Statistical Analyses

TOTAL GALACTOSE (mg Gal/dL whole blood)

Method	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 421 - Enriched 5 mg/dL whole blood						
Fluorometric Manual	137	5.9	0.9	1.2	0.8	1.0
Bioassay	10	4.4	0.6	0.6	0.0	0.8
Fluor Cont Flow, Kit	30	7.6	0.7	1.5	2.1	1.0
Colorimetric	40	7.2	1.1	1.4	0.6	1.3
Neo-Genesis (Neomet) Accuwell	30	6.3	0.4	0.6	0.2	1.1
Bio-Rad Quantase	116	6.8	0.8	1.4	0.1	1.3
MP Biomedicals (ICN) Enzyme	30	9.6	0.7	2.1	3.3	1.3
Interscientific Enzyme	39	6.0	0.3	0.4	0.3	1.1
Astoria-Pacific	40	9.1	0.7	0.7	2.8	1.1
Other	70	6.7	1.7	1.9	0.7	1.1
Lot 422 - Enriched 10 mg/dL whole blood						
Fluorometric Manual	138	11.0	1.2	1.4	0.8	1.0
Bioassay	10	7.6	0.8	0.8	0.0	0.8
Fluor Cont Flow, Kit	30	12.1	1.0	1.7	2.1	1.0
Colorimetric	40	13.1	1.6	1.8	0.6	1.3
Neo-Genesis (Neomet) Accuwell	30	10.6	1.0	1.5	0.2	1.1
Bio-Rad Quantase	119	12.6	1.3	1.9	0.1	1.3
MP Biomedicals (ICN) Enzyme	30	17.4	1.3	3.6	3.3	1.3
Interscientific Enzyme	39	10.9	1.1	1.1	0.3	1.1
Astoria-Pacific	40	13.9	0.9	1.1	2.8	1.1
Other	68	11.2	1.4	1.7	0.7	1.1

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

TOTAL GALACTOSE (mg Gal/dL whole blood)
- continued -

Method	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 423 - Enriched 15 mg/dL whole blood						
Fluorometric Manual	140	15.6	1.4	1.6	0.8	1.0
Bioassay	10	10.6	1.6	1.6	0.0	0.8
Fluor Cont Flow, Kit	30	17.3	0.8	1.9	2.1	1.0
Colorimetric	40	19.6	2.5	3.1	0.6	1.3
Neo-Genesis (Neomet) Accuwell	30	15.7	1.4	1.5	0.2	1.1
Bio-Rad Quantase	118	19.5	1.9	3.4	0.1	1.3
MP Biomedicals (ICN) Enzyme	30	23.4	1.7	4.9	3.3	1.3
Interscientific Enzyme	38	15.4	1.3	2.2	0.3	1.1
Astoria-Pacific	39	19.3	0.9	1.1	2.8	1.1
Other	67	16.4	2.2	2.8	0.7	1.1
Lot 424 - Enriched 30 mg/dL whole blood						
Fluorometric Manual	142	30.9	2.9	3.8	0.8	1.0
Bioassay	10	23.3	3.2	3.2	0.0	0.8
Fluor Cont Flow, Kit	30	33.2	2.2	2.7	2.1	1.0
Colorimetric	39	38.8	4.4	5.0	0.6	1.3
Neo-Genesis (Neomet) Accuwell	30	33.0	2.7	3.4	0.2	1.1
Bio-Rad Quantase	119	38.7	3.7	8.3	0.1	1.3
MP Biomedicals (ICN) Enzyme	20	43.6	0.9	2.9	3.3	1.3
Interscientific Enzyme	40	32.3	2.3	2.9	0.3	1.1
Astoria-Pacific	39	37.3	1.5	1.8	2.8	1.1
Other	68	33.5	4.0	6.1	0.7	1.1

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

TOTAL GALACTOSE (mg Gal/dL whole blood)
- continued -

Method	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 425 - Enriched 5 mg/dL whole blood						
Fluorometric Manual	254	5.5	1.0	1.3	-0.4	1.1
Bioassay	20	3.5	0.8	0.8	-0.4	0.8
Fluor Cont Flow, Kit	50	6.5	0.6	1.2	0.7	1.0
Colorimetric	100	6.6	1.1	2.3	0.0	1.2
Neo-Genesis (Neomet) Accuwell	60	6.3	0.7	0.7	0.2	1.0
Bio-Rad Quantase	238	6.5	1.0	1.6	-0.1	1.2
MP Biomedicals (ICN) Enzyme	80	9.5	0.8	1.2	1.5	1.5
Interscientific Enzyme	60	4.7	0.7	0.7	-0.8	1.0
Astoria-Pacific	113	7.3	0.6	1.5	1.0	1.1
Other	160	6.3	1.1	1.9	0.8	1.0
Lot 426 - Enriched 10 mg/dL whole blood						
Fluorometric Manual	255	10.5	1.0	1.1	-0.4	1.1
Bioassay	20	7.5	0.8	0.8	-0.4	0.8
Fluor Cont Flow, Kit	50	11.5	1.0	1.4	0.7	1.0
Colorimetric	102	11.6	1.9	3.3	0.0	1.2
Neo-Genesis (Neomet) Accuwell	60	10.8	1.2	1.3	0.2	1.0
Bio-Rad Quantase	233	12.2	1.4	2.0	-0.1	1.2
MP Biomedicals (ICN) Enzyme	80	16.7	1.3	2.4	1.5	1.5
Interscientific Enzyme	61	9.7	1.1	1.1	-0.8	1.0
Astoria-Pacific	114	12.5	0.8	2.1	1.0	1.1
Other	157	11.2	1.6	2.4	0.8	1.0

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

TOTAL GALACTOSE (mg Gal/dL whole blood)
- continued -

Method	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 427 - Enriched 15 mg/dL whole blood						
Fluorometric Manual	260	14.8	1.9	2.2	-0.4	1.1
Bioassay	20	10.8	1.3	1.3	-0.4	0.8
Fluor Cont Flow, Kit	49	15.1	1.2	2.0	0.7	1.0
Colorimetric	100	15.9	2.0	4.3	0.0	1.2
Neo-Genesis (Neomet) Accuwell	60	14.3	1.8	1.8	0.2	1.0
Bio-Rad Quantase	234	16.1	2.0	2.8	-0.1	1.2
MP Biomedicals (ICN) Enzyme	80	22.9	1.9	2.5	1.5	1.5
Interscientific Enzyme	47	13.8	0.7	0.7	-0.8	1.0
Astoria-Pacific	113	16.4	1.1	2.5	1.0	1.1
Other	157	15.4	2.0	3.0	0.8	1.0
Lot 428 - Enriched 30 mg/dL whole blood						
Fluorometric Manual	253	32.2	2.7	3.2	-0.4	1.1
Bioassay	20	22.9	2.1	2.1	-0.4	0.8
Fluor Cont Flow, Kit	48	32.7	1.7	3.0	0.7	1.0
Colorimetric	100	35.4	4.3	8.6	0.0	1.2
Neo-Genesis (Neomet) Accuwell	60	32.2	4.6	5.2	0.2	1.0
Bio-Rad Quantase	241	36.0	3.9	6.3	-0.1	1.2
MP Biomedicals (ICN) Enzyme	50	47.2	2.1	5.3	1.5	1.5
Interscientific Enzyme	50	30.5	1.7	2.2	-0.8	1.0
Astoria-Pacific	115	35.2	2.2	5.0	1.0	1.1
Other	156	31.9	3.7	7.7	0.8	1.0

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

TOTAL GALACTOSE (mg Gal/dL whole blood)
- continued -

Method	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 521 - Enriched 5 mg/dL whole blood						
Fluorometric Manual	110	5.6	0.6	0.9	0.5	1.1
Bioassay	10	3.1	0.4	0.4	0.0	0.8
Fluor Cont Flow, Kit	20	6.7	0.6	0.6	1.6	1.0
Colorimetric	60	6.8	1.5	2.7	1.0	1.1
Neo-Genesis (Neomet) Accuwell	30	5.7	0.6	0.6	0.2	1.0
Bio-Rad Quantase	126	5.8	0.9	1.3	-0.2	1.1
MP Biomedicals (ICN) Enzyme	50	9.1	0.9	1.3	1.6	1.5
Interscientific Enzyme	20	4.9	0.5	0.5	-0.7	1.1
Astoria-Pacific	85	7.6	0.6	1.9	1.3	1.2
Other	89	6.2	0.9	1.5	1.2	1.0
Lot 522 - Enriched 10 mg/dL whole blood						
Fluorometric Manual	108	11.0	0.8	1.6	0.5	1.1
Bioassay	10	8.8	0.4	0.4	0.0	0.8
Fluor Cont Flow, Kit	20	11.7	0.9	0.9	1.6	1.0
Colorimetric	58	12.3	1.9	4.2	1.0	1.1
Neo-Genesis (Neomet) Accuwell	29	10.5	0.6	0.7	0.2	1.0
Bio-Rad Quantase	129	11.0	1.2	1.8	-0.2	1.1
MP Biomedicals (ICN) Enzyme	50	16.2	1.1	2.4	1.6	1.5
Interscientific Enzyme	20	10.0	0.3	0.3	-0.7	1.1
Astoria-Pacific	87	12.8	0.8	2.0	1.3	1.2
Other	89	11.0	1.2	1.8	1.2	1.0

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

TOTAL GALACTOSE (mg Gal/dL whole blood)
- continued -

Method	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 523 - Enriched 15 mg/dL whole blood						
Fluorometric Manual	105	16.4	1.2	2.0	0.5	1.1
Bioassay	10	12.4	1.3	1.3	0.0	0.8
Fluor Cont Flow, Kit	20	16.5	0.8	1.4	1.6	1.0
Colorimetric	60	17.8	2.8	6.2	1.0	1.1
Neo-Genesis (Neomet) Accuwell	30	15.7	1.3	1.4	0.2	1.0
Bio-Rad Quantase	124	16.7	1.6	2.5	-0.2	1.1
MP Biomedicals (ICN) Enzyme	50	24.6	1.5	2.9	1.6	1.5
Interscientific Enzyme	20	15.1	0.8	0.8	-0.7	1.1
Astoria-Pacific	87	18.7	1.5	2.1	1.3	1.2
Other	90	16.4	1.3	3.2	1.2	1.0
Lot 524 - Enriched 30 mg/dL whole blood						
Fluorometric Manual	105	31.9	2.2	3.2	0.5	1.1
Bioassay	10	23.7	1.2	1.2	0.0	0.8
Fluor Cont Flow, Kit	20	31.8	1.8	2.8	1.6	1.0
Colorimetric	59	35.0	4.7	10.9	1.0	1.1
Neo-Genesis (Neomet) Accuwell	29	31.8	2.4	2.4	0.2	1.0
Bio-Rad Quantase	127	34.3	4.3	6.1	-0.2	1.1
MP Biomedicals (ICN) Enzyme	39	46.6	2.9	5.7	1.6	1.5
Interscientific Enzyme	20	31.6	2.4	2.4	-0.7	1.1
Astoria-Pacific	86	36.8	2.3	3.5	1.3	1.2
Other	89	31.1	2.9	6.3	1.2	1.0

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

TABLE 7e. 2005 Quality Control Data
Summaries of Statistical Analyses

PHENYLALANINE (mg Phe/dL whole blood)

Method	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 421 - Nonenriched 0 mg/dL whole blood						
Bacterial Inhibition Assays	60	1.6	0.4	0.5	1.7	0.9
Fluorometric Manual	70	1.9	0.2	0.2	2.0	1.0
Fluor Cont Flo, In house	22	2.3	0.2	0.8	2.3	1.2
Fluor cont Flo, Kit	130	1.9	0.2	0.4	2.1	1.0
Colorimetric	78	1.9	0.2	0.3	2.1	1.2
PerkinElmer Neonatal Kit	236	1.4	0.2	0.3	1.5	0.9
Neo-Genesis (Neomet) Accuwell	39	1.9	0.3	0.4	1.9	1.1
Bio-Rad Quantase	98	1.8	0.4	0.6	1.7	1.0
MP Biomedicals (ICN) Enzyme	28	1.2	0.2	0.2	1.1	1.0
Interscientific Enzyme	60	1.4	0.2	0.2	1.5	0.9
HPLC	59	1.4	0.2	0.2	1.5	0.9
Derivatized-MS/MS Non-Kit	425	1.6	0.2	0.3	1.6	1.0
Non-derivatized MS/MS Non-Kit	62	1.6	0.2	0.3	1.7	1.0
Deriv-MS/MS PE NeoGram	120	1.6	0.1	0.2	1.7	0.9
Non-deriv-MS/MS PE NeoGram	10	1.3	0.1	0.1	1.3	1.2
Other	30	2.2	0.3	0.8	2.3	1.0
Lot 422 - Enriched 3 mg/dL whole blood						
Bacterial Inhibition Assays	67	4.5	0.6	0.8	1.7	0.9
Fluorometric Manual	69	5.1	0.4	0.6	2.0	1.0
Fluor Cont Flo, In house	22	5.9	0.5	1.8	2.3	1.2
Fluor cont Flo, Kit	129	5.0	0.3	0.7	2.1	1.0
Colorimetric	82	5.8	0.5	0.6	2.1	1.2
PerkinElmer Neonatal Kit	233	4.0	0.4	0.6	1.5	0.9
Neo-Genesis (Neomet) Accuwell	40	4.8	0.5	0.6	1.9	1.1
Bio-Rad Quantase	100	4.6	0.6	0.9	1.7	1.0
MP Biomedicals (ICN) Enzyme	30	3.9	0.6	0.7	1.1	1.0
Interscientific Enzyme	58	4.1	0.4	0.4	1.5	0.9
HPLC	69	4.3	0.3	0.5	1.5	0.9
Derivatized-MS/MS Non-Kit	424	4.5	0.4	0.8	1.6	1.0
Non-derivatized MS/MS Non-Kit	59	4.8	0.7	0.8	1.7	1.0
Deriv-MS/MS PE NeoGram	118	4.4	0.4	0.6	1.7	0.9
Non-deriv-MS/MS PE NeoGram	10	4.7	0.5	0.5	1.3	1.2
Other	30	5.3	0.5	0.6	2.3	1.0

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

PHENYLALANINE (mg Phe/dL whole blood)
- continued -

Method	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 423 - Enriched 7 mg/dL whole blood						
Bacterial Inhibition Assays	70	8.4	0.8	0.9	1.7	0.9
Fluorometric Manual	70	9.4	0.8	1.0	2.0	1.0
Fluor Cont Flo, In house	21	10.9	1.0	2.8	2.3	1.2
Fluor cont Flo, Kit	132	9.1	0.6	1.4	2.1	1.0
Colorimetric	80	11.2	0.8	1.2	2.1	1.2
PerkinElmer Neonatal Kit	230	7.8	0.7	1.1	1.5	0.9
Neo-Genesis (Neomet) Accuwell	39	9.6	0.8	0.9	1.9	1.1
Bio-Rad Quantase	100	9.1	0.9	1.7	1.7	1.0
MP Biomedicals (ICN) Enzyme	29	8.4	0.7	0.7	1.1	1.0
Interscientific Enzyme	60	8.4	0.8	1.0	1.5	0.9
HPLC	59	8.3	0.5	0.6	1.5	0.9
Derivatized-MS/MS Non-Kit	430	8.6	0.8	1.4	1.6	1.0
Non-derivatized MS/MS Non-Kit	59	9.3	1.3	1.5	1.7	1.0
Deriv-MS/MS PE NeoGram	119	8.1	0.7	1.0	1.7	0.9
Non-deriv-MS/MS PE NeoGram	10	9.6	0.9	0.9	1.3	1.2
Other	29	9.3	0.9	1.2	2.3	1.0
Lot 424 - Enriched 11 mg/dL whole blood						
Bacterial Inhibition Assays	67	11.7	1.2	1.2	1.7	0.9
Fluorometric Manual	72	13.0	1.3	1.5	2.0	1.0
Fluor Cont Flo, In house	21	15.9	1.2	4.1	2.3	1.2
Fluor cont Flo, Kit	129	12.3	0.8	2.0	2.1	1.0
Colorimetric	87	15.4	1.1	1.3	2.1	1.2
PerkinElmer Neonatal Kit	223	10.9	1.0	1.7	1.5	0.9
Neo-Genesis (Neomet) Accuwell	48	13.4	1.2	1.7	1.9	1.1
Bio-Rad Quantase	97	13.1	1.2	1.7	1.7	1.0
MP Biomedicals (ICN) Enzyme	30	12.3	1.1	1.2	1.1	1.0
Interscientific Enzyme	59	11.5	1.0	1.2	1.5	0.9
HPLC	70	11.6	0.7	1.3	1.5	0.9
Derivatized-MS/MS Non-Kit	425	12.2	1.0	2.0	1.6	1.0
Non-derivatized MS/MS Non-Kit	60	12.9	1.7	2.2	1.7	1.0
Deriv-MS/MS PE NeoGram	119	11.5	1.0	1.6	1.7	0.9
Non-deriv-MS/MS PE NeoGram	10	14.0	1.5	1.5	1.3	1.2
Other	30	13.2	1.5	2.0	2.3	1.0

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

PHENYLALANINE (mg Phe/dL whole blood)
- continued -

Method	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 425 - Nonenriched 0 mg/dL whole blood						
Bacterial Inhibition Assays	106	1.5	0.4	0.5	1.4	1.0
Fluorometric Manual	209	1.5	0.2	0.4	1.4	1.1
Fluor Cont Flo, In house	59	1.8	0.2	0.4	1.5	1.3
Fluor cont Flo, Kit	239	1.5	0.2	0.3	1.5	1.1
Colorimetric	168	1.4	0.2	0.3	1.3	1.3
PerkinElmer Neonatal Kit	537	1.2	0.2	0.3	1.2	1.0
Neo-Genesis (Neomet) Accuwell	79	1.6	0.3	0.4	1.4	1.1
Bio-Rad Quantase	203	1.4	0.4	0.4	1.3	1.1
MP Biomedicals (ICN) Enzyme	40	1.1	0.3	0.3	1.1	1.1
Interscientific Enzyme	97	1.3	0.2	0.2	1.2	1.0
Thin-Layer Chromatography	10	1.4	0.2	0.2	1.3	0.8
HPLC	108	1.2	0.1	0.2	1.1	1.0
Derivatized-MS/MS Non-Kit	959	1.3	0.2	0.2	1.2	1.0
Non-derivatized MS/MS Non-Kit	137	1.4	0.3	0.4	1.3	1.1
Deriv-MS/MS PE NeoGram	274	1.3	0.2	0.2	1.2	1.0
Non-deriv-MS/MS PE NeoGram	30	1.3	0.1	0.1	1.1	1.1
Other	80	2.0	0.3	0.5	1.8	1.1
Lot 426 - Enriched 3 mg/dL whole blood						
Bacterial Inhibition Assays	128	4.3	0.6	0.7	1.4	1.0
Fluorometric Manual	204	4.6	0.4	0.6	1.4	1.1
Fluor Cont Flo, In house	60	5.1	0.3	1.0	1.5	1.3
Fluor cont Flo, Kit	236	4.7	0.4	0.7	1.5	1.1
Colorimetric	166	5.2	0.4	0.5	1.3	1.3
PerkinElmer Neonatal Kit	511	4.0	0.4	0.6	1.2	1.0
Neo-Genesis (Neomet) Accuwell	78	4.5	0.5	0.5	1.4	1.1
Bio-Rad Quantase	208	4.3	0.5	0.6	1.3	1.1
MP Biomedicals (ICN) Enzyme	49	4.5	0.5	0.5	1.1	1.1
Interscientific Enzyme	99	4.2	0.4	0.4	1.2	1.0
Thin-Layer Chromatography	20	4.0	0.5	0.6	1.3	0.8
HPLC	119	4.1	0.3	0.4	1.1	1.0
Derivatized-MS/MS Non-Kit	980	4.2	0.5	0.7	1.2	1.0
Non-derivatized MS/MS Non-Kit	137	4.6	0.7	0.8	1.3	1.1
Deriv-MS/MS PE NeoGram	280	4.1	0.4	0.5	1.2	1.0
Non-deriv-MS/MS PE NeoGram	30	4.1	0.2	0.2	1.1	1.1
Other	78	5.0	0.5	0.6	1.8	1.1

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

PHENYLALANINE (mg Phe/dL whole blood)
- continued -

Method	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 427 - Enriched 7 mg/dL whole blood						
Bacterial Inhibition Assays	137	8.3	1.0	1.1	1.4	1.0
Fluorometric Manual	207	8.8	0.7	1.1	1.4	1.1
Fluor Cont Flo, In house	60	10.2	0.8	2.0	1.5	1.3
Fluor cont Flo, Kit	237	8.9	0.7	1.2	1.5	1.1
Colorimetric	167	10.0	0.8	1.0	1.3	1.3
PerkinElmer Neonatal Kit	525	7.9	0.8	1.3	1.2	1.0
Neo-Genesis (Neomet) Accuwell	78	8.9	0.7	0.8	1.4	1.1
Bio-Rad Quantase	208	8.7	0.8	1.1	1.3	1.1
MP Biomedicals (ICN) Enzyme	39	8.1	0.8	0.9	1.1	1.1
Interscientific Enzyme	98	8.2	1.0	1.0	1.2	1.0
Thin-Layer Chromatography	20	6.4	0.6	3.3	1.3	0.8
HPLC	106	8.3	0.8	1.0	1.1	1.0
Derivatized-MS/MS Non-Kit	974	8.1	0.9	1.2	1.2	1.0
Non-derivatized MS/MS Non-Kit	137	9.2	0.9	1.3	1.3	1.1
Deriv-MS/MS PE NeoGram	278	7.9	0.8	1.0	1.2	1.0
Non-deriv-MS/MS PE NeoGram	30	8.5	0.6	0.8	1.1	1.1
Other	79	9.3	1.0	1.1	1.8	1.1
Lot 428 - Enriched 11 mg/dL whole blood						
Bacterial Inhibition Assays	137	12.3	1.4	1.6	1.4	1.0
Fluorometric Manual	191	13.3	1.2	1.8	1.4	1.1
Fluor Cont Flo, In house	60	15.8	1.3	3.0	1.5	1.3
Fluor cont Flo, Kit	237	13.3	1.1	2.0	1.5	1.1
Colorimetric	151	15.5	1.0	1.2	1.3	1.3
PerkinElmer Neonatal Kit	510	12.0	1.2	2.0	1.2	1.0
Neo-Genesis (Neomet) Accuwell	72	13.7	1.3	1.3	1.4	1.1
Bio-Rad Quantase	204	13.1	1.4	1.7	1.3	1.1
MP Biomedicals (ICN) Enzyme	48	13.0	1.0	1.6	1.1	1.1
Interscientific Enzyme	100	12.6	1.4	1.5	1.2	1.0
Thin-Layer Chromatography	20	10.7	0.6	2.7	1.3	0.8
HPLC	116	12.5	1.0	1.7	1.1	1.0
Derivatized-MS/MS Non-Kit	975	12.5	1.4	1.9	1.2	1.0
Non-derivatized MS/MS Non-Kit	139	13.7	1.7	2.3	1.3	1.1
Deriv-MS/MS PE NeoGram	277	12.0	1.3	1.5	1.2	1.0
Non-deriv-MS/MS PE NeoGram	28	12.9	0.7	0.8	1.1	1.1
Other	79	14.3	1.8	2.2	1.8	1.1

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

PHENYLALANINE (mg Phe/dL whole blood)
- continued -

Method	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 521 - Nonenriched 0 mg/dL whole blood						
Bacterial Inhibition Assays	49	1.4	0.2	0.4	1.3	1.0
Fluorometric Manual	127	1.7	0.2	0.5	1.6	1.1
Fluor Cont Flo, In house	38	2.0	0.2	0.5	1.6	1.4
Fluor cont Flo, Kit	109	1.8	0.2	0.4	1.7	1.1
Colorimetric	86	1.6	0.2	0.2	1.4	1.4
PerkinElmer Neonatal Kit	292	1.4	0.2	0.3	1.3	1.0
Neo-Genesis (Neomet) Accuwell	40	1.7	0.3	0.4	1.5	1.2
Bio-Rad Quantase	89	1.7	0.3	0.6	1.4	1.2
MP Biomedicals (ICN) Enzyme	10	1.3	0.1	0.1	1.2	1.1
Interscientific Enzyme	39	1.5	0.1	0.2	1.4	0.9
Thin-Layer Chromatography	10	1.4	0.1	0.1	1.7	0.7
HPLC	49	1.3	0.1	0.2	1.1	1.1
Derivatized-MS/MS Non-Kit	562	1.4	0.2	0.3	1.3	1.0
Non-derivatized MS/MS Non-Kit	68	1.6	0.2	0.3	1.4	1.2
Deriv-MS/MS PE NeoGram	174	1.5	0.2	0.2	1.4	1.0
Non-Deriv-MS/MS PE NeoGram	20	1.5	0.1	0.2	1.4	1.0
Other	40	2.0	0.5	0.7	1.8	1.1
Lot 522 - Enriched 3 mg/dL whole blood						
Bacterial Inhibition Assays	66	4.3	0.3	0.5	1.3	1.0
Fluorometric Manual	126	4.9	0.6	0.9	1.6	1.1
Fluor Cont Flo, In house	38	5.5	0.3	1.1	1.6	1.4
Fluor cont Flo, Kit	110	5.0	0.4	0.7	1.7	1.1
Colorimetric	86	5.4	0.4	0.6	1.4	1.4
PerkinElmer Neonatal Kit	284	4.3	0.4	0.7	1.3	1.0
Neo-Genesis (Neomet) Accuwell	39	4.8	0.4	0.4	1.5	1.2
Bio-Rad Quantase	89	4.8	0.5	0.5	1.4	1.2
MP Biomedicals (ICN) Enzyme	20	4.8	0.5	0.5	1.2	1.1
Interscientific Enzyme	40	4.2	0.3	0.4	1.4	0.9
Thin-Layer Chromatography	10	4.1	0.3	0.3	1.7	0.7
HPLC	49	4.4	0.3	0.3	1.1	1.1
Derivatized-MS/MS Non-Kit	555	4.4	0.4	0.6	1.3	1.0
Non-derivatized MS/MS Non-Kit	69	4.9	0.5	0.7	1.4	1.2
Deriv-MS/MS PE NeoGram	177	4.4	0.4	0.6	1.4	1.0
Non-Deriv-MS/MS PE NeoGram	20	4.4	0.4	0.4	1.4	1.0
Other	40	5.1	0.7	0.7	1.8	1.1

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

PHENYLALANINE (mg Phe/dL whole blood)
- continued -

Method	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 523 - Enriched 7 mg/dL whole blood						
Bacterial Inhibition Assays	67	8.5	0.8	1.6	1.3	1.0
Fluorometric Manual	126	8.9	0.8	1.3	1.6	1.1
Fluor Cont Flo, In house	38	10.1	0.6	2.2	1.6	1.4
Fluor cont Flo, Kit	107	9.3	0.7	1.3	1.7	1.1
Colorimetric	84	10.6	0.7	0.9	1.4	1.4
PerkinElmer Neonatal Kit	282	8.2	0.7	1.2	1.3	1.0
Neo-Genesis (Neomet) Accuwell	39	9.4	0.7	0.8	1.5	1.2
Bio-Rad Quantase	88	9.5	0.9	1.4	1.4	1.2
MP Biomedicals (ICN) Enzyme	20	8.2	0.8	1.6	1.2	1.1
Interscientific Enzyme	40	7.8	0.6	0.8	1.4	0.9
Thin-Layer Chromatography	20	6.1	0.5	2.6	1.7	0.7
HPLC	49	8.7	0.6	1.0	1.1	1.1
Derivatized-MS/MS Non-Kit	566	8.3	0.8	1.4	1.3	1.0
Non-derivatized MS/MS Non-Kit	70	9.1	0.9	1.3	1.4	1.2
Deriv-MS/MS PE NeoGram	176	8.1	0.8	1.0	1.4	1.0
Non-Deriv-MS/MS PE NeoGram	20	8.3	0.6	0.6	1.4	1.0
Other	40	9.2	1.0	1.2	1.8	1.1
Lot 524 - Enriched 11 mg/dL whole blood						
Bacterial Inhibition Assays	68	12.6	1.9	2.4	1.3	1.0
Fluorometric Manual	126	13.9	1.4	2.2	1.6	1.1
Fluor Cont Flo, In house	28	17.3	1.2	3.8	1.6	1.4
Fluor cont Flo, Kit	109	14.1	0.9	1.9	1.7	1.1
Colorimetric	88	16.6	1.1	1.7	1.4	1.4
PerkinElmer Neonatal Kit	275	12.8	1.1	1.8	1.3	1.0
Neo-Genesis (Neomet) Accuwell	38	14.5	0.9	0.9	1.5	1.2
Bio-Rad Quantase	85	15.0	1.6	2.7	1.4	1.2
MP Biomedicals (ICN) Enzyme	19	13.6	1.0	2.2	1.2	1.1
Interscientific Enzyme	40	11.9	1.1	1.1	1.4	0.9
Thin-Layer Chromatography	20	8.9	0.5	4.7	1.7	0.7
HPLC	50	13.9	0.9	1.9	1.1	1.1
Derivatized-MS/MS Non-Kit	569	13.0	1.2	2.2	1.3	1.0
Non-derivatized MS/MS Non-Kit	69	14.5	1.3	2.0	1.4	1.2
Deriv-MS/MS PE NeoGram	175	12.5	1.1	1.5	1.4	1.0
Non-Deriv-MS/MS PE NeoGram	20	12.9	0.9	0.9	1.4	1.0
Other	39	14.2	1.6	1.6	1.8	1.1

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

TABLE 7f. 2005 Quality Control Data
Summaries of Statistical Analyses

LEUCINE (mg Leu/dL whole blood)

Method	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 421 - Nonenriched 0 mg/dL whole blood						
Bacterial Inhibition Assays	10	2.7	0.8	0.8	1.8	1.3
Bio-Rad Quantase	10	3.7	0.6	0.6	3.5	1.3
Thin-Layer Chromatography	10	1.8	0.4	0.4	1.7	0.9
HPLC	30	1.9	0.2	0.2	1.9	1.2
Derivatized-MS/MS Non-Kit	384	2.5	0.3	0.6	2.5	1.0
Non-derivatized MS/MS Non-Kit	28	2.4	0.2	0.2	2.5	0.9
Deriv-MS/MS PE NeoGram	118	2.4	0.3	0.3	2.4	0.9
Non-deriv MS/MS PE NeoGram	10	2.4	0.3	0.3	2.4	1.3
Other	10	3.7	1.0	1.0	3.9	1.6
Lot 422 - Enriched 3 mg/dL whole blood						
Bacterial Inhibition Assays	10	5.2	2.4	2.4	1.8	1.3
Bio-Rad Quantase	10	7.1	0.8	0.8	3.5	1.3
Thin-Layer Chromatography	10	4.1	0.6	0.6	1.7	0.9
HPLC	30	5.2	0.3	0.5	1.9	1.2
Derivatized-MS/MS Non-Kit	387	5.2	0.5	1.1	2.5	1.0
Non-derivatized MS/MS Non-Kit	30	5.2	0.7	0.7	2.5	0.9
Deriv-MS/MS PE NeoGram	115	5.1	0.5	0.5	2.4	0.9
Non-deriv MS/MS PE NeoGram	10	6.1	0.6	0.6	2.4	1.3
Other	10	8.5	1.6	1.6	3.9	1.6
Lot 423 - Enriched 7 mg/dL whole blood						
Bacterial Inhibition Assays	10	9.6	2.8	2.8	1.8	1.3
Bio-Rad Quantase	10	13.1	1.2	1.2	3.5	1.3
Thin-Layer Chromatography	10	8.3	0.5	0.5	1.7	0.9
HPLC	29	10.7	0.5	1.2	1.9	1.2
Derivatized-MS/MS Non-Kit	382	10.2	1.0	2.1	2.5	1.0
Non-derivatized MS/MS Non-Kit	30	9.9	1.2	1.8	2.5	0.9
Deriv-MS/MS PE NeoGram	118	9.5	0.8	0.9	2.4	0.9
Non-deriv MS/MS PE NeoGram	8	12.1	0.8	0.8	2.4	1.3
Other	10	16.4	2.2	2.2	3.9	1.6
Lot 424 - Enriched 11 mg/dL whole blood						
Bacterial Inhibition Assays	10	17.2	3.8	3.8	1.8	1.3
Bio-Rad Quantase	10	18.3	1.4	1.4	3.5	1.3
Thin-Layer Chromatography	10	11.4	0.5	0.5	1.7	0.9
HPLC	30	14.9	0.8	2.3	1.9	1.2
Derivatized-MS/MS Non-Kit	396	13.2	1.2	2.9	2.5	1.0
Non-derivatized MS/MS Non-Kit	30	12.4	1.4	1.8	2.5	0.9
Deriv-MS/MS PE NeoGram	120	12.5	1.2	1.4	2.4	0.9
Non-deriv MS/MS PE NeoGram	10	16.6	1.8	1.8	2.4	1.3
Other	10	21.2	1.3	1.3	3.9	1.6

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

LEUCINE (mg Leu/dL whole blood)
- continued -

Method	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 425 - Nonenriched 0 mg/dL whole blood						
Bacterial Inhibition Assays	20	1.9	0.2	0.2	1.9	0.9
Bio-Rad Quantase	39	2.5	0.4	0.4	2.4	1.3
Thin-Layer Chromatography	30	2.7	0.6	0.8	2.3	1.1
HPLC	59	1.7	0.2	0.2	1.5	1.3
Derivatized-MS/MS Non-Kit	897	2.1	0.3	0.4	2.1	1.1
Non-derivatized MS/MS Non-Kit	69	2.3	0.4	0.4	2.1	1.1
Deriv-MS/MS PE NeoGram	297	2.1	0.2	0.3	2.0	1.1
Non-deriv MS/MS PE NeoGram	20	2.3	0.2	0.3	2.1	1.0
Other	20	2.7	0.8	0.8	2.2	1.5
Lot 426 - Enriched 3 mg/dL whole blood						
Bacterial Inhibition Assays	19	4.9	0.5	0.5	1.9	0.9
Bio-Rad Quantase	40	6.5	0.5	1.5	2.4	1.3
Thin-Layer Chromatography	30	5.2	0.5	0.5	2.3	1.1
HPLC	59	5.4	0.3	0.5	1.5	1.3
Derivatized-MS/MS Non-Kit	890	5.5	0.6	1.0	2.1	1.1
Non-derivatized MS/MS Non-Kit	69	5.4	0.8	0.8	2.1	1.1
Deriv-MS/MS PE NeoGram	297	5.2	0.5	0.6	2.0	1.1
Non-deriv MS/MS PE NeoGram	20	5.1	0.3	0.5	2.1	1.0
Other	20	6.5	0.7	0.7	2.2	1.5
Lot 427 - Enriched 7 mg/dL whole blood						
Bacterial Inhibition Assays	20	8.3	0.8	1.7	1.9	0.9
Bio-Rad Quantase	40	11.2	1.0	3.0	2.4	1.3
Thin-Layer Chromatography	30	10.1	1.2	2.4	2.3	1.1
HPLC	59	10.4	0.8	1.4	1.5	1.3
Derivatized-MS/MS Non-Kit	897	10.0	1.1	1.8	2.1	1.1
Non-derivatized MS/MS Non-Kit	70	9.9	1.5	1.5	2.1	1.1
Deriv-MS/MS PE NeoGram	296	9.5	0.9	1.1	2.0	1.1
Non-deriv MS/MS PE NeoGram	20	9.4	0.7	1.8	2.1	1.0
Other	19	12.1	1.3	1.3	2.2	1.5
Lot 428 - Enriched 11 mg/dL whole blood						
Bacterial Inhibition Assays	20	12.4	1.3	2.8	1.9	0.9
Bio-Rad Quantase	39	17.3	1.1	4.0	2.4	1.3
Thin-Layer Chromatography	28	14.5	0.9	0.9	2.3	1.1
HPLC	60	16.4	1.1	2.2	1.5	1.3
Derivatized-MS/MS Non-Kit	881	14.8	1.6	2.6	2.1	1.1
Non-derivatized MS/MS Non-Kit	69	14.6	1.9	2.0	2.1	1.1
Deriv-MS/MS PE NeoGram	290	13.7	1.2	1.3	2.0	1.1
Non-deriv MS/MS PE NeoGram	20	13.7	1.2	1.5	2.1	1.0
Other	20	19.3	2.6	2.6	2.2	1.5

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

LEUCINE (mg Leu/dL whole blood)
- continued -

Method	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 521 - Nonenriched 0 mg/dL whole blood						
Bacterial Inhibition Assays	20	2.0	0.2	0.2	0.9	1.2
Bio-Rad Quantase	29	2.7	0.4	0.6	2.5	1.1
Thin-Layer Chromatography	20	3.3	0.4	1.9	3.3	0.6
HPLC	30	1.7	0.1	0.2	1.7	1.1
Derivatized-MS/MS Non-Kit	538	2.2	0.3	0.5	2.2	1.0
Non-derivatized MS/MS Non-Kit	30	2.7	0.3	0.8	2.5	1.0
Deriv-MS/MS PE NeoGram	198	2.2	0.2	0.3	2.1	0.9
Non-deriv MS/MS PE NeoGram	10	2.3	0.2	0.2	2.3	0.8
Lot 522 - Enriched 3 mg/dL whole blood						
Bacterial Inhibition Assays	30	4.6	0.7	0.7	0.9	1.2
Bio-Rad Quantase	30	5.7	0.5	1.7	2.5	1.1
Thin-Layer Chromatography	20	4.9	0.4	0.6	3.3	0.6
HPLC	29	5.1	0.3	0.4	1.7	1.1
Derivatized-MS/MS Non-Kit	522	5.3	0.5	0.9	2.2	1.0
Non-derivatized MS/MS Non-Kit	30	5.5	0.8	1.2	2.5	1.0
Deriv-MS/MS PE NeoGram	194	5.0	0.4	0.6	2.1	0.9
Non-deriv MS/MS PE NeoGram	10	4.7	0.3	0.3	2.3	0.8
Lot 523 - Enriched 7 mg/dL whole blood						
Bacterial Inhibition Assays	28	7.3	1.1	1.3	0.9	1.2
Bio-Rad Quantase	30	9.9	0.8	3.1	2.5	1.1
Thin-Layer Chromatography	20	8.0	0.5	0.8	3.3	0.6
HPLC	29	9.4	0.9	1.4	1.7	1.1
Derivatized-MS/MS Non-Kit	522	9.0	0.8	1.5	2.2	1.0
Non-derivatized MS/MS Non-Kit	29	8.6	1.3	1.7	2.5	1.0
Deriv-MS/MS PE NeoGram	198	8.4	0.7	1.0	2.1	0.9
Non-deriv MS/MS PE NeoGram	10	7.7	0.8	0.8	2.3	0.8
Lot 524 - Enriched 11 mg/dL whole blood						
Bacterial Inhibition Assays	30	15.7	3.5	4.8	0.9	1.2
Bio-Rad Quantase	30	14.9	1.3	4.8	2.5	1.1
Thin-Layer Chromatography	20	9.9	0.7	1.9	3.3	0.6
HPLC	30	14.2	1.3	2.2	1.7	1.1
Derivatized-MS/MS Non-Kit	518	13.5	1.2	2.4	2.2	1.0
Non-derivatized MS/MS Non-Kit	30	13.4	2.1	2.5	2.5	1.0
Deriv-MS/MS PE NeoGram	195	12.7	1.1	1.6	2.1	0.9
Non-deriv MS/MS PE NeoGram	10	11.2	0.8	0.8	2.3	0.8

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

TABLE 7g. 2005 Quality Control Data
Summaries of Statistical Analyses

METHIONINE (mg Met/dL whole blood)

Method	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 421 - Nonenriched 0 mg/dL whole blood						
Thin-Layer Chromatography	10	0.0	0.0	0.0	0.2	0.7
HPLC	29	0.4	0.1	0.1	0.1	1.0
Derivatized-MS/MS Non-Kit	384	0.4	0.1	0.1	0.3	0.9
Non-derivatized MS/MS Non-Kit	20	0.4	0.1	0.2	0.2	0.8
Deriv-MS/MS PE NeoGram	118	0.5	0.1	0.2	0.5	1.0
Non-deriv MS/MS PE NeoGram	10	0.3	0.1	0.1	0.3	0.9
Lot 422 - Enriched 1 mg/dL whole blood						
Thin-Layer Chromatography	9	1.0	0.0	0.0	0.2	0.7
HPLC	30	1.0	0.1	0.2	0.1	1.0
Derivatized-MS/MS Non-Kit	385	1.2	0.1	0.3	0.3	0.9
Non-derivatized MS/MS Non-Kit	20	1.0	0.3	0.3	0.2	0.8
Deriv-MS/MS PE NeoGram	119	1.5	0.2	0.3	0.5	1.0
Non-deriv MS/MS PE NeoGram	10	1.2	0.1	0.1	0.3	0.9
Lot 423 - Enriched 3 mg/dL whole blood						
Thin-Layer Chromatography	10	2.6	0.5	0.5	0.2	0.7
HPLC	30	2.7	0.2	0.3	0.1	1.0
Derivatized-MS/MS Non-Kit	382	3.0	0.3	0.6	0.3	0.9
Non-derivatized MS/MS Non-Kit	20	2.6	0.3	0.3	0.2	0.8
Deriv-MS/MS PE NeoGram	120	3.4	0.3	0.5	0.5	1.0
Non-deriv MS/MS PE NeoGram	10	2.9	0.3	0.3	0.3	0.9
Lot 424 - Enriched 6 mg/dL whole blood						
Thin-Layer Chromatography	10	4.4	0.5	0.5	0.2	0.7
HPLC	30	6.2	0.4	0.4	0.1	1.0
Derivatized-MS/MS Non-Kit	383	5.9	0.6	1.2	0.3	0.9
Non-derivatized MS/MS Non-Kit	19	5.3	0.5	0.5	0.2	0.8
Deriv-MS/MS PE NeoGram	120	6.5	0.7	1.0	0.5	1.0
Non-deriv MS/MS PE NeoGram	10	5.6	0.5	0.5	0.3	0.9

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

METHIONINE (mg Met/dL whole blood)
- continued -

Method	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 425 - Nonenriched 0 mg/dL whole blood						
Thin-Layer Chromatography	30	0.3	0.3	0.7	1.0	0.8
HPLC	49	0.3	0.1	0.1	0.1	0.9
Derivatized-MS/MS Non-Kit	883	0.3	0.1	0.1	0.3	0.8
Non-derivatized MS/MS Non-Kit	57	0.3	0.1	0.1	0.2	0.8
Deriv-MS/MS PE NeoGram	289	0.4	0.1	0.1	0.4	0.9
Non-deriv MS/MS PE NeoGram	20	0.3	0.1	0.1	0.2	0.8
Lot 426 - Enriched 1 mg/dL whole blood						
Thin-Layer Chromatography	30	3.3	0.4	4.8	1.0	0.8
HPLC	48	1.0	0.1	0.2	0.1	0.9
Derivatized-MS/MS Non-Kit	876	1.2	0.2	0.2	0.3	0.8
Non-derivatized MS/MS Non-Kit	59	1.0	0.3	0.3	0.2	0.8
Deriv-MS/MS PE NeoGram	297	1.3	0.2	0.2	0.4	0.9
Non-deriv MS/MS PE NeoGram	20	1.0	0.1	0.2	0.2	0.8
Lot 427 - Enriched 3 mg/dL whole blood						
Thin-Layer Chromatography	30	2.3	0.4	0.6	1.0	0.8
HPLC	51	2.6	0.5	0.5	0.1	0.9
Derivatized-MS/MS Non-Kit	886	2.8	0.3	0.6	0.3	0.8
Non-derivatized MS/MS Non-Kit	59	2.3	0.6	0.6	0.2	0.8
Deriv-MS/MS PE NeoGram	296	3.0	0.4	0.4	0.4	0.9
Non-deriv MS/MS PE NeoGram	20	2.5	0.2	0.6	0.2	0.8
Lot 428 - Enriched 6 mg/dL whole blood						
Thin-Layer Chromatography	30	6.1	0.6	2.6	1.0	0.8
HPLC	44	5.6	0.5	0.7	0.1	0.9
Derivatized-MS/MS Non-Kit	867	5.4	0.6	1.0	0.3	0.8
Non-derivatized MS/MS Non-Kit	58	4.9	1.0	1.1	0.2	0.8
Deriv-MS/MS PE NeoGram	298	5.7	0.7	0.8	0.4	0.9
Non-deriv MS/MS PE NeoGram	20	5.0	0.3	0.7	0.2	0.8

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

METHIONINE (mg Met/dL whole blood)
- continued -

Method	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 521 - Nonenriched 0 mg/dL whole blood						
Thin-Layer Chromatography	20	1.1	0.4	1.6	1.0	0.7
HPLC	19	0.3	0.1	0.1	0.2	1.0
Derivatized-MS/MS Non-Kit	506	0.3	0.1	0.1	0.3	0.9
Non-derivatized MS/MS Non-Kit	27	0.3	0.1	0.1	0.2	0.8
Deriv-MS/MS PE NeoGram	191	0.4	0.1	0.1	0.3	0.9
Non-deriv MS/MS PE NeoGram	10	0.3	0.1	0.1	0.3	0.8
Lot 522 - Enriched 1 mg/dL whole blood						
Thin-Layer Chromatography	20	1.7	0.3	0.9	1.0	0.7
HPLC	20	1.1	0.1	0.2	0.2	1.0
Derivatized-MS/MS Non-Kit	508	1.2	0.1	0.2	0.3	0.9
Non-derivatized MS/MS Non-Kit	30	1.0	0.2	0.3	0.2	0.8
Deriv-MS/MS PE NeoGram	197	1.3	0.2	0.2	0.3	0.9
Non-deriv MS/MS PE NeoGram	10	1.1	0.1	0.1	0.3	0.8
Lot 523 - Enriched 3 mg/dL whole blood						
Thin-Layer Chromatography	20	2.7	0.6	0.6	1.0	0.7
HPLC	19	3.2	0.2	0.2	0.2	1.0
Derivatized-MS/MS Non-Kit	504	2.9	0.3	0.5	0.3	0.9
Non-derivatized MS/MS Non-Kit	30	2.5	0.4	0.5	0.2	0.8
Deriv-MS/MS PE NeoGram	197	3.0	0.3	0.4	0.3	0.9
Non-deriv MS/MS PE NeoGram	10	2.7	0.3	0.3	0.3	0.8
Lot 524 - Enriched 6 mg/dL whole blood						
Thin-Layer Chromatography	20	5.4	0.6	1.0	1.0	0.7
HPLC	20	6.1	0.2	0.3	0.2	1.0
Derivatized-MS/MS Non-Kit	507	5.7	0.5	0.9	0.3	0.9
Non-derivatized MS/MS Non-Kit	30	5.1	1.0	1.4	0.2	0.8
Deriv-MS/MS PE NeoGram	194	5.9	0.6	0.8	0.3	0.9
Non-deriv MS/MS PE NeoGram	10	5.0	0.4	0.4	0.3	0.8

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

TABLE 7h. 2005 Quality Control Data
Summaries of Statistical Analyses

TYROSINE (mg Tyr/dL whole blood)

Method	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 421 - Nonenriched 0 mg/dL whole blood						
Fluor Cont Flo, Kit	20	2.2	0.2	0.3	2.1	1.2
Thin-Layer Chromatography	10	0.7	0.5	0.5	0.9	0.9
HPLC	49	1.3	0.1	0.4	1.2	1.0
Derivatized-MS/MS Non-Kit	386	1.3	0.1	0.3	1.2	0.9
Non-derivatized MS/MS Non-Kit	40	1.4	0.3	0.4	1.3	1.0
Deriv-MS/MS PE NeoGram	119	1.3	0.1	0.2	1.2	0.9
Non-deriv MS/MS PE NeoGram	10	1.1	0.1	0.1	1.1	1.0
Other	10	2.9	0.4	0.4	3.0	0.9
Lot 422 - Enriched 1 mg/dL whole blood						
Fluor Cont Flo, Kit	20	3.3	0.3	0.5	2.1	1.2
Thin-Layer Chromatography	10	1.8	0.4	0.4	0.9	0.9
HPLC	58	2.2	0.1	0.5	1.2	1.0
Derivatized-MS/MS Non-Kit	383	2.1	0.2	0.4	1.2	0.9
Non-derivatized MS/MS Non-Kit	40	2.4	0.4	0.5	1.3	1.0
Deriv-MS/MS PE NeoGram	119	2.2	0.2	0.3	1.2	0.9
Non-deriv MS/MS PE NeoGram	10	2.1	0.2	0.2	1.1	1.0
Other	10	4.0	0.6	0.6	3.0	0.9
Lot 423 - Enriched 3 mg/dL whole blood						
Fluor Cont Flo, Kit	20	5.4	0.3	1.0	2.1	1.2
Thin-Layer Chromatography	10	3.6	0.5	0.5	0.9	0.9
HPLC	50	4.1	0.3	0.6	1.2	1.0
Derivatized-MS/MS Non-Kit	391	3.9	0.4	0.8	1.2	0.9
Non-derivatized MS/MS Non-Kit	40	4.2	0.6	0.9	1.3	1.0
Deriv-MS/MS PE NeoGram	119	3.8	0.4	0.5	1.2	0.9
Non-deriv MS/MS PE NeoGram	10	4.2	0.4	0.4	1.1	1.0
Other	10	5.7	0.5	0.5	3.0	0.9
Lot 424 - Enriched 8 mg/dL whole blood						
Fluor Cont Flo, Kit	20	11.4	0.8	2.2	2.1	1.2
Thin-Layer Chromatography	10	7.6	0.5	0.5	0.9	0.9
HPLC	59	9.3	0.6	1.0	1.2	1.0
Derivatized-MS/MS Non-Kit	394	8.5	0.8	1.6	1.2	0.9
Non-derivatized MS/MS Non-Kit	40	9.5	1.1	2.3	1.3	1.0
Deriv-MS/MS PE NeoGram	119	8.6	0.9	1.1	1.2	0.9
Non-deriv MS/MS PE NeoGram	10	9.0	0.9	0.9	1.1	1.0
Other	9	10.5	0.8	0.8	3.0	0.9

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

TYROSINE (mg Tyr/dL whole blood)
- continued -

Method	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 425 - Nonenriched 0 mg/dL whole blood						
Bacterial Inhibition	10	0.8	0.1	0.1	0.8	0.6
Fluorometric Manual	10	2.0	0.3	0.3	1.9	1.1
Fluor Cont Flo, Kit	20	1.9	0.2	0.4	1.8	1.2
Thin-Layer Chromatography	19	1.0	0.0	0.0	1.1	0.8
HPLC	87	1.1	0.1	0.3	1.0	1.0
Derivatized-MS/MS Non-Kit	896	1.1	0.1	0.2	1.1	0.9
Non-derivatized MS/MS Non-Kit	78	1.3	0.2	0.3	1.2	1.0
Deriv-MS/MS PE NeoGram	286	1.1	0.1	0.1	1.1	0.9
Non-deriv MS/MS PE NeoGram	20	1.1	0.1	0.1	1.0	0.9
Lot 426 - Enriched 1 mg/dL whole blood						
Bacterial Inhibition	10	1.4	0.2	0.2	0.8	0.6
Fluorometric Manual	10	2.9	0.3	0.3	1.9	1.1
Fluor Cont Flo, Kit	20	2.9	0.3	0.8	1.8	1.2
Thin-Layer Chromatography	20	2.0	0.0	0.0	1.1	0.8
HPLC	95	2.0	0.2	0.4	1.0	1.0
Derivatized-MS/MS Non-Kit	885	2.0	0.2	0.4	1.1	0.9
Non-derivatized MS/MS Non-Kit	76	2.2	0.3	0.5	1.2	1.0
Deriv-MS/MS PE NeoGram	288	2.0	0.2	0.3	1.1	0.9
Non-deriv MS/MS PE NeoGram	20	1.9	0.2	0.2	1.0	0.9
Lot 427 - Enriched 3 mg/dL whole blood						
Bacterial Inhibition	10	2.7	0.3	0.3	0.8	0.6
Fluorometric Manual	10	4.9	0.7	0.7	1.9	1.1
Fluor Cont Flo, Kit	20	5.2	0.4	1.6	1.8	1.2
Thin-Layer Chromatography	20	3.5	0.5	0.5	1.1	0.8
HPLC	88	3.8	0.3	0.6	1.0	1.0
Derivatized-MS/MS Non-Kit	878	3.7	0.4	0.7	1.1	0.9
Non-derivatized MS/MS Non-Kit	78	4.3	0.6	1.0	1.2	1.0
Deriv-MS/MS PE NeoGram	289	3.8	0.4	0.6	1.1	0.9
Non-deriv MS/MS PE NeoGram	20	3.7	0.4	0.6	1.0	0.9
Lot 428 - Enriched 8 mg/dL whole blood						
Bacterial Inhibition	10	5.9	0.8	0.8	0.8	0.6
Fluorometric Manual	10	10.6	0.6	0.6	1.9	1.1
Fluor Cont Flo, Kit	20	11.2	0.9	2.9	1.8	1.2
Thin-Layer Chromatography	20	7.3	0.5	0.5	1.1	0.8
HPLC	97	8.7	0.6	1.3	1.0	1.0
Derivatized-MS/MS Non-Kit	875	8.3	0.8	1.4	1.1	0.9
Non-derivatized MS/MS Non-Kit	80	9.2	1.4	2.2	1.2	1.0
Deriv-MS/MS PE NeoGram	286	8.2	0.9	1.0	1.1	0.9
Non-deriv MS/MS PE NeoGram	20	8.3	0.8	1.0	1.0	0.9

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

TYROSINE (mg Tyr/dL whole blood)
- continued -

Method	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 521 - Nonenriched 0 mg/dL whole blood						
Bacterial Inhibition	10	0.9	0.1	0.1	0.9	0.6
Fluorometric Manual	10	2.2	0.3	0.3	2.1	1.1
Thin-Layer Chromatography	9	1.0	0.0	0.0	1.0	0.7
HPLC	40	1.0	0.1	0.2	1.0	0.9
Derivatized-MS/MS Non-Kit	514	1.1	0.1	0.2	1.0	1.0
Non-derivatized MS/MS Non-Kit	40	1.2	0.2	0.3	1.2	1.0
Deriv-MS/MS PE NeoGram	197	1.1	0.1	0.2	1.0	0.9
Non-deriv MS/MS PE NeoGram	10	1.1	0.1	0.1	0.9	0.9
Lot 522 - Enriched 1 mg/dL whole blood						
Bacterial Inhibition	10	1.6	0.2	0.2	0.9	0.6
Fluorometric Manual	10	3.1	0.4	0.4	2.1	1.1
Thin-Layer Chromatography	10	1.7	0.5	0.5	1.0	0.7
HPLC	40	2.0	0.2	0.3	1.0	0.9
Derivatized-MS/MS Non-Kit	510	2.0	0.2	0.4	1.0	1.0
Non-derivatized MS/MS Non-Kit	40	2.1	0.2	0.5	1.2	1.0
Deriv-MS/MS PE NeoGram	199	2.0	0.2	0.3	1.0	0.9
Non-deriv MS/MS PE NeoGram	9	1.8	0.1	0.1	0.9	0.9
Lot 523 - Enriched 3 mg/dL whole blood						
Bacterial Inhibition	10	3.0	0.5	0.5	0.9	0.6
Fluorometric Manual	10	5.3	0.8	0.8	2.1	1.1
Thin-Layer Chromatography	9	3.0	0.0	0.0	1.0	0.7
HPLC	39	3.7	0.2	0.4	1.0	0.9
Derivatized-MS/MS Non-Kit	511	3.8	0.4	0.7	1.0	1.0
Non-derivatized MS/MS Non-Kit	40	4.1	0.5	0.9	1.2	1.0
Deriv-MS/MS PE NeoGram	197	3.6	0.4	0.6	1.0	0.9
Non-deriv MS/MS PE NeoGram	10	3.1	0.3	0.3	0.9	0.9
Lot 524 - Enriched 8 mg/dL whole blood						
Bacterial Inhibition	10	6.0	0.6	0.6	0.9	0.6
Fluorometric Manual	10	10.9	0.5	0.5	2.1	1.1
Thin-Layer Chromatography	10	6.7	0.7	0.7	1.0	0.7
HPLC	40	8.5	0.5	0.8	1.0	0.9
Derivatized-MS/MS Non-Kit	521	8.7	0.9	1.8	1.0	1.0
Non-derivatized MS/MS Non-Kit	37	9.0	0.9	1.9	1.2	1.0
Deriv-MS/MS PE NeoGram	197	8.3	0.9	1.3	1.0	0.9
Non-deriv MS/MS PE NeoGram	10	7.9	1.3	1.3	0.9	0.9

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

TABLE 7i. 2005 Quality Control Data
Summaries of Statistical Analyses

VALINE (mg Val/dL whole blood)

Method	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 421 - Nonenriched 0 mg/dL whole blood						
Thin-Layer Chromatography	10	1.4	0.5	0.5	1.4	0.6
HPLC	29	2.2	0.1	0.3	2.1	1.1
Derivatized-MS/MS Non-Kit	325	2.3	0.3	0.6	2.2	0.9
Non-derivatized MS/MS Non-Kit	20	1.8	0.2	0.2	1.7	0.8
Deriv-MS/MS PE NeoGram	109	1.7	0.2	0.3	1.7	0.7
Non-deriv MS/MS PE NeoGram	10	1.9	0.4	0.4	1.9	0.9
Lot 422 - Enriched 1 mg/dL whole blood						
Thin-Layer Chromatography	10	2.2	0.4	0.4	1.4	0.6
HPLC	29	3.4	0.2	0.4	2.1	1.1
Derivatized-MS/MS Non-Kit	325	3.0	0.3	0.8	2.2	0.9
Non-derivatized MS/MS Non-Kit	20	2.5	0.3	0.3	1.7	0.8
Deriv-MS/MS PE NeoGram	109	2.5	0.4	0.4	1.7	0.7
Non-deriv MS/MS PE NeoGram	10	2.8	0.3	0.3	1.9	0.9
Lot 423 - Enriched 3 mg/dL whole blood						
Thin-Layer Chromatography	10	3.0	0.0	0.0	1.4	0.6
HPLC	30	4.9	0.4	0.8	2.1	1.1
Derivatized-MS/MS Non-Kit	326	4.5	0.5	1.0	2.2	0.9
Non-derivatized MS/MS Non-Kit	20	3.9	0.7	0.9	1.7	0.8
Deriv-MS/MS PE NeoGram	109	3.6	0.4	0.6	1.7	0.7
Non-deriv MS/MS PE NeoGram	10	4.8	0.4	0.4	1.9	0.9
Lot 424 - Enriched 6 mg/dL whole blood						
Thin-Layer Chromatography	10	5.0	0.7	0.7	1.4	0.6
HPLC	30	9.0	0.6	0.6	2.1	1.1
Derivatized-MS/MS Non-Kit	330	7.4	0.8	1.7	2.2	0.9
Non-derivatized MS/MS Non-Kit	20	6.4	0.7	1.2	1.7	0.8
Deriv-MS/MS PE NeoGram	109	5.9	0.6	0.9	1.7	0.7
Non-deriv MS/MS PE NeoGram	10	7.4	0.8	0.8	1.9	0.9

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

VALINE (mg Val/dL whole blood)
- continued -

Method	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 425 - Nonenriched 0 mg/dL whole blood						
Thin-Layer Chromatography	30	1.4	0.4	0.4	1.5	0.6
HPLC	58	1.9	0.2	0.2	1.8	1.1
Derivatized-MS/MS Non-Kit	781	1.8	0.3	0.5	1.8	0.8
Non-derivatized MS/MS Non-Kit	39	1.4	0.2	0.2	1.4	0.7
Deriv-MS/MS PE NeoGram	226	1.4	0.2	0.2	1.4	0.7
Non-deriv MS/MS PE NeoGram	20	1.6	0.1	0.1	1.5	0.8
Lot 426 - Enriched 1 mg/dL whole blood						
Thin-Layer Chromatography	30	2.2	0.4	0.5	1.5	0.6
HPLC	60	2.9	0.2	0.3	1.8	1.1
Derivatized-MS/MS Non-Kit	783	2.6	0.4	0.7	1.8	0.8
Non-derivatized MS/MS Non-Kit	40	2.2	0.3	0.3	1.4	0.7
Deriv-MS/MS PE NeoGram	224	2.1	0.3	0.4	1.4	0.7
Non-deriv MS/MS PE NeoGram	20	2.3	0.2	0.3	1.5	0.8
Lot 427 - Enriched 3 mg/dL whole blood						
Thin-Layer Chromatography	30	3.4	0.5	0.5	1.5	0.6
HPLC	59	4.8	0.4	0.5	1.8	1.1
Derivatized-MS/MS Non-Kit	782	4.2	0.5	1.0	1.8	0.8
Non-derivatized MS/MS Non-Kit	40	3.6	0.4	0.4	1.4	0.7
Deriv-MS/MS PE NeoGram	225	3.6	0.5	0.7	1.4	0.7
Non-deriv MS/MS PE NeoGram	20	3.9	0.2	0.8	1.5	0.8
Lot 428 - Enriched 6 mg/dL whole blood						
Thin-Layer Chromatography	30	5.2	0.8	0.9	1.5	0.6
HPLC	58	8.2	0.6	0.9	1.8	1.1
Derivatized-MS/MS Non-Kit	776	6.7	0.9	1.5	1.8	0.8
Non-derivatized MS/MS Non-Kit	39	5.9	0.6	0.6	1.4	0.7
Deriv-MS/MS PE NeoGram	223	5.8	0.8	1.1	1.4	0.7
Non-deriv MS/MS PE NeoGram	20	6.0	0.8	1.3	1.5	0.8

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

VALINE (mg Val/dL whole blood)
- continued -

Method	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 521 - Nonenriched 0 mg/dL whole blood						
Thin-Layer Chromatography	20	1.4	0.4	0.4	1.4	0.6
HPLC	30	2.1	0.1	0.2	2.0	0.9
Derivatized-MS/MS Non-Kit	454	2.0	0.3	0.5	1.9	0.8
Non-derivatized MS/MS Non-Kit	20	1.7	0.3	0.3	1.6	0.6
Deriv-MS/MS PE NeoGram	166	1.7	0.2	0.4	1.6	0.7
Non-deriv MS/MS PE NeoGram	10	1.7	0.1	0.1	1.6	0.6
Lot 522 - Enriched 1 mg/dL whole blood						
Thin-Layer Chromatography	20	2.2	0.4	0.4	1.4	0.6
HPLC	29	3.0	0.2	0.2	2.0	0.9
Derivatized-MS/MS Non-Kit	463	2.6	0.3	0.6	1.9	0.8
Non-derivatized MS/MS Non-Kit	20	2.2	0.3	0.3	1.6	0.6
Deriv-MS/MS PE NeoGram	167	2.2	0.3	0.6	1.6	0.7
Non-deriv MS/MS PE NeoGram	10	2.2	0.2	0.2	1.6	0.6
Lot 523 - Enriched 3 mg/dL whole blood						
Thin-Layer Chromatography	20	3.1	0.4	0.6	1.4	0.6
HPLC	30	4.9	0.4	0.5	2.0	0.9
Derivatized-MS/MS Non-Kit	459	4.0	0.5	0.9	1.9	0.8
Non-derivatized MS/MS Non-Kit	20	3.4	0.4	0.4	1.6	0.6
Deriv-MS/MS PE NeoGram	165	3.4	0.3	0.7	1.6	0.7
Non-deriv MS/MS PE NeoGram	10	3.4	0.3	0.3	1.6	0.6
Lot 524 - Enriched 6 mg/dL whole blood						
Thin-Layer Chromatography	20	5.1	0.5	0.5	1.4	0.6
HPLC	30	7.7	0.6	0.7	2.0	0.9
Derivatized-MS/MS Non-Kit	458	6.6	0.7	1.5	1.9	0.8
Non-derivatized MS/MS Non-Kit	20	5.5	0.7	0.7	1.6	0.6
Deriv-MS/MS PE NeoGram	167	5.7	0.6	1.2	1.6	0.7
Non-deriv MS/MS PE NeoGram	10	5.5	0.4	0.4	1.6	0.6

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

TABLE 7j. 2005 Quality Control Data
Summaries of Statistical Analyses

CITRULLINE (mg Cit/dL whole blood)

Method	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 421 - Nonenriched 0 mg/dL whole blood						
Thin-Layer Chromatography	9	0.0	0.0	0.0	0.0	0.8
Derivatized-MS/MS Non-Kit	349	0.5	0.1	0.1	0.5	0.7
Non-derivatized MS/MS Non-Kit	18	0.4	0.2	0.2	0.4	0.6
Deriv-MS/MS PE NeoGram	118	0.6	0.1	0.1	0.6	1.0
Non-deriv MS/MS PE NeoGram	10	0.6	0.1	0.1	0.7	2.5
Lot 422 - Enriched 0.5 mg/dL whole blood						
Thin-Layer Chromatography	10	0.2	0.4	0.4	0.0	0.8
Derivatized-MS/MS Non-Kit	349	0.8	0.1	0.3	0.5	0.7
Non-derivatized MS/MS Non-Kit	18	0.7	0.2	0.2	0.4	0.6
Deriv-MS/MS PE NeoGram	117	1.1	0.1	0.1	0.6	1.0
Non-deriv MS/MS PE NeoGram	10	1.7	0.1	0.1	0.7	2.5
Lot 423 - Enriched 1 mg/dL whole blood						
Thin-Layer Chromatography	9	1.0	0.0	0.0	0.0	0.8
Derivatized-MS/MS Non-Kit	353	1.2	0.2	0.4	0.5	0.7
Non-derivatized MS/MS Non-Kit	17	1.1	0.2	0.2	0.4	0.6
Deriv-MS/MS PE NeoGram	118	1.5	0.1	0.2	0.6	1.0
Non-deriv MS/MS PE NeoGram	10	3.8	0.4	0.4	0.7	2.5
Lot 424 - Enriched 2.5 mg/dL whole blood						
Thin-Layer Chromatography	10	2.0	0.0	0.0	0.0	0.8
Derivatized-MS/MS Non-Kit	360	2.2	0.4	0.7	0.5	0.7
Non-derivatized MS/MS Non-Kit	18	2.0	0.5	0.5	0.4	0.6
Deriv-MS/MS PE NeoGram	118	3.0	0.2	0.4	0.6	1.0
Non-deriv MS/MS PE NeoGram	10	6.9	0.7	0.7	0.7	2.5

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

CITRULLINE (mg Cit/dL whole blood)
- continued -

Method	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 425 - Nonenriched 0 mg/dL whole blood						
Thin-Layer Chromatography	20	0.0	0.0	0.0	0.1	0.7
Derivatized-MS/MS Non-Kit	796	0.4	0.1	0.1	0.4	0.7
Non-derivatized MS/MS Non-Kit	38	0.4	0.1	0.1	0.4	0.6
Deriv-MS/MS PE NeoGram	260	0.5	0.1	0.1	0.5	0.9
Non-deriv MS/MS PE NeoGram	20	0.6	0.1	0.1	0.5	0.6
Lot 426 - Enriched 1 mg/dL whole blood						
Thin-Layer Chromatography	19	0.9	0.2	0.2	0.1	0.7
Derivatized-MS/MS Non-Kit	796	1.1	0.2	0.4	0.4	0.7
Non-derivatized MS/MS Non-Kit	40	1.0	0.2	0.2	0.4	0.6
Deriv-MS/MS PE NeoGram	266	1.4	0.1	0.2	0.5	0.9
Non-deriv MS/MS PE NeoGram	20	1.2	0.1	0.4	0.5	0.6
Lot 427 - Enriched 3 mg/dL whole blood						
Thin-Layer Chromatography	20	2.0	0.0	0.0	0.1	0.7
Derivatized-MS/MS Non-Kit	800	2.4	0.4	0.6	0.4	0.7
Non-derivatized MS/MS Non-Kit	40	2.3	0.6	0.6	0.4	0.6
Deriv-MS/MS PE NeoGram	265	3.2	0.3	0.4	0.5	0.9
Non-deriv MS/MS PE NeoGram	20	2.4	0.2	1.0	0.5	0.6
Lot 428 - Enriched 6 mg/dL whole blood						
Thin-Layer Chromatography	20	4.1	0.5	0.5	0.1	0.7
Derivatized-MS/MS Non-Kit	792	4.5	0.7	1.2	0.4	0.7
Non-derivatized MS/MS Non-Kit	39	4.2	1.1	1.1	0.4	0.6
Deriv-MS/MS PE NeoGram	267	6.0	0.6	0.8	0.5	0.9
Non-deriv MS/MS PE NeoGram	20	4.5	0.4	2.2	0.5	0.6

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

CITRULLINE (mg Cit/dL whole blood)
- continued -

Method	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 521 - Nonenriched 0 mg/dL whole blood						
Thin-Layer Chromatography	10	0.0	0.0	0.0	0.2	0.6
Derivatized-MS/MS Non-Kit	470	0.4	0.1	0.1	0.4	0.8
Non-derivatized MS/MS Non-Kit	20	0.4	0.1	0.1	0.4	0.7
Deriv-MS/MS PE NeoGram	177	0.5	0.1	0.1	0.4	1.0
Non-deriv MS/MS PE NeoGram	10	0.6	0.1	0.1	0.5	1.0
Lot 522 - Enriched 1 mg/dL whole blood						
Thin-Layer Chromatography	10	1.0	0.0	0.0	0.2	0.6
Derivatized-MS/MS Non-Kit	472	1.1	0.2	0.3	0.4	0.8
Non-derivatized MS/MS Non-Kit	20	1.1	0.2	0.2	0.4	0.7
Deriv-MS/MS PE NeoGram	173	1.5	0.1	0.2	0.4	1.0
Non-deriv MS/MS PE NeoGram	10	1.4	0.1	0.1	0.5	1.0
Lot 523 - Enriched 3 mg/dL whole blood						
Thin-Layer Chromatography	10	2.0	0.0	0.0	0.2	0.6
Derivatized-MS/MS Non-Kit	471	2.6	0.3	0.7	0.4	0.8
Non-derivatized MS/MS Non-Kit	20	2.6	0.6	0.6	0.4	0.7
Deriv-MS/MS PE NeoGram	178	3.4	0.3	0.5	0.4	1.0
Non-deriv MS/MS PE NeoGram	10	3.3	0.3	0.3	0.5	1.0
Lot 524 - Enriched 6 mg/dL whole blood						
Thin-Layer Chromatography	10	3.7	0.5	0.5	0.2	0.6
Derivatized-MS/MS Non-Kit	472	4.9	0.6	1.2	0.4	0.8
Non-derivatized MS/MS Non-Kit	20	4.7	1.0	1.0	0.4	0.7
Deriv-MS/MS PE NeoGram	179	6.5	0.5	0.9	0.4	1.0
Non-deriv MS/MS PE NeoGram	10	6.3	0.3	0.3	0.5	1.0

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

TABLE 7k. 2005 Quality Control Data
Summaries of Statistical Analyses

ACETYLCARNITINE (μmol C2/L whole blood)

Method	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 461 - Nonenriched 0 μmol/L whole blood						
Derivatized-MS/MS Non-Kit	554	24.46	2.46	5.72	22.49	0.80
Non-derivatized MS/MS Non-Kit	49	20.76	2.46	2.46	19.20	0.71
Deriv-MS/MS PE NeoGram	89	27.99	2.92	3.73	26.25	0.46
Non-deriv MS/MS PE NeoGram	30	23.19	1.82	2.31	21.29	0.94
Lot 462 - Enriched 5 μmol/L whole blood						
Derivatized-MS/MS Non-Kit	555	25.68	2.60	5.72	22.49	0.80
Non-derivatized MS/MS Non-Kit	49	22.36	2.72	2.91	19.20	0.71
Deriv-MS/MS PE NeoGram	88	27.70	2.71	3.45	26.25	0.46
Non-deriv MS/MS PE NeoGram	30	25.32	3.08	3.23	21.29	0.94
Lot 463 - Enriched 10 μmol/L whole blood						
Derivatized-MS/MS Non-Kit	552	27.79	2.66	5.87	22.49	0.80
Non-derivatized MS/MS Non-Kit	49	23.83	2.76	3.31	19.20	0.71
Deriv-MS/MS PE NeoGram	88	28.63	2.69	3.48	26.25	0.46
Non-deriv MS/MS PE NeoGram	29	27.84	2.74	3.53	21.29	0.94
Lot 464 - Enriched 20 μmol/L whole blood						
Derivatized-MS/MS Non-Kit	556	40.07	3.83	8.67	22.49	0.80
Non-derivatized MS/MS Non-Kit	49	34.79	4.40	5.11	19.20	0.71
Deriv-MS/MS PE NeoGram	88	36.84	3.68	5.17	26.25	0.46
Non-deriv MS/MS PE NeoGram	30	41.67	2.47	3.33	21.29	0.94

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

TABLE 7l. 2005 Quality Control Data
Summaries of Statistical Analyses

PROPIONYLCARNITINE (μmol C3/L whole blood)

Method	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 461 - Nonenriched 0 μmol/L whole blood						
Derivatized-MS/MS Non-Kit	1109	2.18	0.33	0.43	1.96	1.12
Non-derivatized MS/MS Non-Kit	75	2.00	0.36	0.42	1.89	1.17
Deriv-MS/MS PE NeoGram	231	2.01	0.28	0.36	1.74	1.08
Non-deriv MS/MS PE NeoGram	60	2.09	0.20	0.26	1.91	1.08
Lot 462 - Enriched 3 μmol/L whole blood						
Derivatized-MS/MS Non-Kit	1092	5.01	0.68	0.89	1.96	1.12
Non-derivatized MS/MS Non-Kit	78	5.12	0.88	0.91	1.89	1.17
Deriv-MS/MS PE NeoGram	230	4.68	0.56	0.71	1.74	1.08
Non-deriv MS/MS PE NeoGram	58	4.84	0.47	0.54	1.91	1.08
Lot 463 - Enriched 7.5 μmol/L whole blood						
Derivatized-MS/MS Non-Kit	1109	10.34	1.44	2.03	1.96	1.12
Non-derivatized MS/MS Non-Kit	77	10.86	2.01	2.98	1.89	1.17
Deriv-MS/MS PE NeoGram	231	9.69	1.14	1.55	1.74	1.08
Non-deriv MS/MS PE NeoGram	60	10.13	0.95	1.15	1.91	1.08
Lot 464 - Enriched 12 μmol/L whole blood						
Derivatized-MS/MS Non-Kit	1091	15.41	2.03	2.95	1.96	1.12
Non-derivatized MS/MS Non-Kit	78	15.79	2.75	3.37	1.89	1.17
Deriv-MS/MS PE NeoGram	231	14.83	1.65	2.32	1.74	1.08
Non-deriv MS/MS PE NeoGram	59	14.89	1.13	1.71	1.91	1.08

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

PROPIONYLCARNITINE (μmol C3/L whole blood)
- continued -

Method	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 561 - Nonenriched 0 μmol/L whole blood						
Derivatized-MS/MS Non-Kit	619	2.07	0.29	0.41	2.14	1.07
Non-derivatized MS/MS Non-Kit	27	2.19	0.45	0.60	2.51	1.07
Deriv-MS/MS PE NeoGram	163	1.81	0.19	0.28	1.78	1.00
Non-deriv MS/MS PE NeoGram	36	1.93	0.31	0.34	2.06	0.93
Lot 562 - Enriched 3 μmol/L whole blood						
Derivatized-MS/MS Non-Kit	624	5.42	0.66	0.94	2.14	1.07
Non-derivatized MS/MS Non-Kit	30	5.67	0.62	1.46	2.51	1.07
Deriv-MS/MS PE NeoGram	164	4.74	0.38	0.72	1.78	1.00
Non-deriv MS/MS PE NeoGram	35	5.13	0.66	0.82	2.06	0.93
Lot 563 - Enriched 7.5 μmol/L whole blood						
Derivatized-MS/MS Non-Kit	623	10.28	1.06	1.70	2.14	1.07
Non-derivatized MS/MS Non-Kit	30	11.34	2.68	2.85	2.51	1.07
Deriv-MS/MS PE NeoGram	170	9.26	0.85	1.49	1.78	1.00
Non-deriv MS/MS PE NeoGram	39	8.82	1.26	1.71	2.06	0.93
Lot 564 - Enriched 12 μmol/L whole blood						
Derivatized-MS/MS Non-Kit	619	14.94	1.60	2.67	2.14	1.07
Non-derivatized MS/MS Non-Kit	34	14.84	5.00	5.91	2.51	1.07
Deriv-MS/MS PE NeoGram	158	13.74	1.19	2.07	1.78	1.00
Non-deriv MS/MS PE NeoGram	37	13.27	1.57	2.31	2.06	0.93

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

TABLE 7m. 2005 Quality Control Data
Summaries of Statistical Analyses

BUTYRYLCARNITINE (μmol C4/L whole blood)

Method	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 461 - Nonenriched 0 μmol/L whole blood						
Derivatized-MS/MS Non-Kit	1097	0.29	0.07	0.10	0.25	0.89
Non-derivatized MS/MS Non-Kit	78	0.34	0.13	0.20	0.26	0.85
Deriv-MS/MS PE NeoGram	213	0.29	0.09	0.09	0.25	0.80
Non-deriv MS/MS PE NeoGram	58	0.31	0.12	0.13	0.25	0.91
Lot 462 - Enriched 1 μmol/L whole blood						
Derivatized-MS/MS Non-Kit	1085	1.11	0.16	0.23	0.25	0.89
Non-derivatized MS/MS Non-Kit	80	1.06	0.22	0.29	0.26	0.85
Deriv-MS/MS PE NeoGram	217	1.02	0.19	0.20	0.25	0.80
Non-deriv MS/MS PE NeoGram	60	1.14	0.25	0.26	0.25	0.91
Lot 463 - Enriched 2.5 μmol/L whole blood						
Derivatized-MS/MS Non-Kit	1094	2.42	0.35	0.50	0.25	0.89
Non-derivatized MS/MS Non-Kit	79	2.30	0.40	0.48	0.26	0.85
Deriv-MS/MS PE NeoGram	217	2.20	0.37	0.41	0.25	0.80
Non-deriv MS/MS PE NeoGram	58	2.43	0.33	0.36	0.25	0.91
Lot 464 - Enriched 5 μmol/L whole blood						
Derivatized-MS/MS Non-Kit	1086	4.71	0.63	0.96	0.25	0.89
Non-derivatized MS/MS Non-Kit	83	4.56	0.85	0.90	0.26	0.85
Deriv-MS/MS PE NeoGram	219	4.27	0.63	0.75	0.25	0.80
Non-deriv MS/MS PE NeoGram	59	4.84	0.72	0.87	0.25	0.91

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

BUTYRYLCARNITINE (μmol C4/L whole blood)
- continued -

Method	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 561 - Nonenriched 0 μmol/L whole blood						
Derivatized-MS/MS Non-Kit	626	0.31	0.07	0.11	0.34	0.89
Non-derivatized MS/MS Non-Kit	30	0.36	0.11	0.30	0.29	0.83
Deriv-MS/MS PE NeoGram	168	0.31	0.07	0.08	0.31	0.82
Non-deriv MS/MS PE NeoGram	37	0.32	0.11	0.12	0.37	0.82
Lot 562 - Enriched 1 μmol/L whole blood						
Derivatized-MS/MS Non-Kit	632	1.25	0.18	0.25	0.34	0.89
Non-derivatized MS/MS Non-Kit	30	1.10	0.15	0.28	0.29	0.83
Deriv-MS/MS PE NeoGram	165	1.14	0.19	0.22	0.31	0.82
Non-deriv MS/MS PE NeoGram	39	1.27	0.28	0.37	0.37	0.82
Lot 563 - Enriched 2.5 μmol/L whole blood						
Derivatized-MS/MS Non-Kit	627	2.63	0.33	0.50	0.34	0.89
Non-derivatized MS/MS Non-Kit	29	2.25	0.28	0.46	0.29	0.83
Deriv-MS/MS PE NeoGram	168	2.34	0.35	0.41	0.31	0.82
Non-deriv MS/MS PE NeoGram	39	2.39	0.48	0.50	0.37	0.82
Lot 564 - Enriched 5 μmol/L whole blood						
Derivatized-MS/MS Non-Kit	631	4.79	0.60	0.87	0.34	0.89
Non-derivatized MS/MS Non-Kit	26	4.51	0.51	0.83	0.29	0.83
Deriv-MS/MS PE NeoGram	167	4.41	0.68	0.77	0.31	0.82
Non-deriv MS/MS PE NeoGram	38	4.49	0.61	0.81	0.37	0.82

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

TABLE 7n. 2005 Quality Control Data
Summaries of Statistical Analyses

ISOVALERYLCARNITINE (μmol C5/L whole blood)

Method	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 461 - Nonenriched 0 μmol/L whole blood						
Derivatized-MS/MS Non-Kit	1066	0.19	0.04	0.06	0.16	1.06
Non-derivatized MS/MS Non-Kit	77	0.16	0.06	0.07	0.12	0.93
Deriv-MS/MS PE NeoGram	234	0.21	0.05	0.06	0.17	0.99
Non-deriv MS/MS PE NeoGram	58	0.17	0.05	0.06	0.14	0.94
Lot 462 - Enriched 0.5 μmol/L whole blood						
Derivatized-MS/MS Non-Kit	1088	0.65	0.10	0.15	0.16	1.06
Non-derivatized MS/MS Non-Kit	78	0.55	0.13	0.15	0.12	0.93
Deriv-MS/MS PE NeoGram	236	0.63	0.12	0.13	0.17	0.99
Non-deriv MS/MS PE NeoGram	59	0.57	0.12	0.13	0.14	0.94
Lot 463 - Enriched 1.5 μmol/L whole blood						
Derivatized-MS/MS Non-Kit	1085	1.74	0.24	0.36	0.16	1.06
Non-derivatized MS/MS Non-Kit	79	1.51	0.28	0.32	0.12	0.93
Deriv-MS/MS PE NeoGram	242	1.63	0.28	0.30	0.17	0.99
Non-deriv MS/MS PE NeoGram	58	1.57	0.25	0.32	0.14	0.94
Lot 464 - Enriched 3 μmol/L whole blood						
Derivatized-MS/MS Non-Kit	1090	3.33	0.41	0.69	0.16	1.06
Non-derivatized MS/MS Non-Kit	81	2.92	0.53	0.63	0.12	0.93
Deriv-MS/MS PE NeoGram	243	3.15	0.43	0.48	0.17	0.99
Non-deriv MS/MS PE NeoGram	59	2.96	0.47	0.53	0.14	0.94

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

ISOVALERYLCARNITINE (μmol C5/L whole blood)
- continued -

Method	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 561 - Nonenriched 0 μmol/L whole blood						
Derivatized-MS/MS Non-Kit	619	0.20	0.04	0.08	0.20	0.98
Non-derivatized MS/MS Non-Kit	29	0.16	0.03	0.04	0.11	0.94
Deriv-MS/MS PE NeoGram	168	0.20	0.05	0.06	0.19	0.97
Non-deriv MS/MS PE NeoGram	39	0.19	0.08	0.09	0.17	0.78
Lot 562 - Enriched 0.5 μmol/L whole blood						
Derivatized-MS/MS Non-Kit	622	0.70	0.10	0.17	0.20	0.98
Non-derivatized MS/MS Non-Kit	30	0.57	0.09	0.12	0.11	0.94
Deriv-MS/MS PE NeoGram	169	0.68	0.12	0.13	0.19	0.97
Non-deriv MS/MS PE NeoGram	39	0.57	0.15	0.16	0.17	0.78
Lot 563 - Enriched 1.5 μmol/L whole blood						
Derivatized-MS/MS Non-Kit	608	1.67	0.21	0.36	0.20	0.98
Non-derivatized MS/MS Non-Kit	28	1.43	0.19	0.27	0.11	0.94
Deriv-MS/MS PE NeoGram	165	1.62	0.23	0.26	0.19	0.97
Non-deriv MS/MS PE NeoGram	40	1.26	0.25	0.33	0.17	0.78
Lot 564 - Enriched 3 μmol/L whole blood						
Derivatized-MS/MS Non-Kit	611	3.15	0.40	0.68	0.20	0.98
Non-derivatized MS/MS Non-Kit	27	2.96	0.32	0.36	0.11	0.94
Deriv-MS/MS PE NeoGram	162	3.10	0.42	0.50	0.19	0.97
Non-deriv MS/MS PE NeoGram	39	2.53	0.39	0.53	0.17	0.78

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

TABLE 7o. 2005 Quality Control Data
Summaries of Statistical Analyses

GLUTARYLCARNITINE (μmol C5DC/L whole blood)

Method	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 461 - CDC Assayed 0.07 μmol/L whole blood						
Derivatized-MS/MS Non-Kit	1047	0.05	0.03	0.05	-0.01	0.80
Non-derivatized MS/MS Non-Kit	48	0.02	0.02	0.02	0.00	0.25
Deriv-MS/MS PE NeoGram	233	0.07	0.03	0.04	0.00	0.94
Non-deriv MS/MS PE NeoGram	59	0.25	0.09	0.13	0.09	1.85
Lot 462 - CDC Assayed 0.24 μmol/L whole blood						
Derivatized-MS/MS Non-Kit	1038	0.18	0.06	0.14	-0.01	0.80
Non-derivatized MS/MS Non-Kit	50	0.06	0.03	0.05	0.00	0.25
Deriv-MS/MS PE NeoGram	232	0.23	0.05	0.08	0.00	0.94
Non-deriv MS/MS PE NeoGram	59	0.50	0.09	0.13	0.09	1.85
Lot 463 - CDC Assayed 0.44 μmol/L whole blood						
Derivatized-MS/MS Non-Kit	1028	0.33	0.09	0.20	-0.01	0.80
Non-derivatized MS/MS Non-Kit	49	0.11	0.04	0.08	0.00	0.25
Deriv-MS/MS PE NeoGram	229	0.40	0.08	0.14	0.00	0.94
Non-deriv MS/MS PE NeoGram	60	0.89	0.17	0.33	0.09	1.85
Lot 464 - CDC Assayed 0.78 μmol/L whole blood						
Derivatized-MS/MS Non-Kit	1035	0.62	0.13	0.34	-0.01	0.80
Non-derivatized MS/MS Non-Kit	50	0.19	0.07	0.15	0.00	0.25
Deriv-MS/MS PE NeoGram	228	0.74	0.14	0.28	0.00	0.94
Non-deriv MS/MS PE NeoGram	60	1.55	0.22	0.65	0.09	1.85

Note that for both kit and non-kit users, the calculation of concentrations for the quality control lots varied with type of internal standard. Data are not sorted by internal standard type. In a survey, participants reported using d_9-C5, d_3-C8, d_3-C10, d_3-C12, d_3-C16, or d_6-C5DC as an internal standard for C5DC.

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

GLUTARYLCARNITINE (μmol C5DC/L whole blood)
- continued -

Method	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 561 - CDC Assayed 0.05 μmol/L whole blood						
Derivatized-MS/MS Non-Kit	611	0.05	0.03	0.04	0.01	0.77
Non-derivatized MS/MS Non-Kit	20	0.01	0.01	0.01	0.01	0.10
Deriv-MS/MS PE NeoGram	168	0.06	0.03	0.04	0.00	1.10
Non-deriv MS/MS PE NeoGram	28	0.26	0.08	0.12	0.14	1.82
Lot 562 - CDC Assayed 0.25 μmol/L whole blood						
Derivatized-MS/MS Non-Kit	587	0.20	0.06	0.14	0.01	0.77
Non-derivatized MS/MS Non-Kit	19	0.03	0.02	0.02	0.01	0.10
Deriv-MS/MS PE NeoGram	168	0.27	0.07	0.10	0.00	1.10
Non-deriv MS/MS PE NeoGram	28	0.60	0.08	0.12	0.14	1.82
Lot 563 - CDC Assayed 0.46 μmol/L whole blood						
Derivatized-MS/MS Non-Kit	594	0.36	0.08	0.16	0.01	0.77
Non-derivatized MS/MS Non-Kit	19	0.05	0.02	0.03	0.01	0.10
Deriv-MS/MS PE NeoGram	168	0.50	0.09	0.18	0.00	1.10
Non-deriv MS/MS PE NeoGram	28	0.87	0.12	0.27	0.14	1.82
Lot 564 - CDC Assayed 0.84 μmol/L whole blood						
Derivatized-MS/MS Non-Kit	586	0.66	0.12	0.27	0.01	0.77
Non-derivatized MS/MS Non-Kit	20	0.09	0.04	0.06	0.01	0.10
Deriv-MS/MS PE NeoGram	166	0.92	0.16	0.34	0.00	1.10
Non-deriv MS/MS PE NeoGram	28	1.71	0.26	0.75	0.14	1.82

Note that for both kit and non-kit users, the calculation of concentrations for the quality control lots varied with type of internal standard. Data are not sorted by internal standard type. In a survey, participants reported using d_9-C5, d_3-C8, d_3-C10, d_3-C12, d_3-C16, or d_6-C5DC as an internal standard for C5DC.

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

TABLE 7p. 2005 Quality Control Data
Summaries of Statistical Analyses

HEXANOYLCARNITINE (μmol C6/L whole blood)

Method	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 461 - Nonenriched 0 μmol/L whole blood						
Derivatized-MS/MS Non-Kit	1051	0.05	0.03	0.04	0.03	0.90
Non-derivatized MS/MS Non-Kit	58	0.02	0.02	0.02	0.00	0.83
Deriv-MS/MS PE NeoGram	235	0.05	0.03	0.03	0.03	0.86
Non-deriv MS/MS PE NeoGram	48	0.03	0.02	0.02	0.01	0.85
Lot 462 - Enriched 0.5 μmol/L whole blood						
Derivatized-MS/MS Non-Kit	1055	0.45	0.08	0.12	0.03	0.90
Non-derivatized MS/MS Non-Kit	60	0.39	0.08	0.10	0.00	0.83
Deriv-MS/MS PE NeoGram	244	0.44	0.09	0.10	0.03	0.86
Non-deriv MS/MS PE NeoGram	49	0.42	0.07	0.08	0.01	0.85
Lot 463 - Enriched 1 μmol/L whole blood						
Derivatized-MS/MS Non-Kit	1060	0.94	0.17	0.24	0.03	0.90
Non-derivatized MS/MS Non-Kit	59	0.82	0.15	0.20	0.00	0.83
Deriv-MS/MS PE NeoGram	238	0.88	0.16	0.18	0.03	0.86
Non-deriv MS/MS PE NeoGram	49	0.84	0.16	0.17	0.01	0.85
Lot 464 - Enriched 2.5 μmol/L whole blood						
Derivatized-MS/MS Non-Kit	1052	2.28	0.32	0.52	0.03	0.90
Non-derivatized MS/MS Non-Kit	59	2.07	0.29	0.43	0.00	0.83
Deriv-MS/MS PE NeoGram	238	2.19	0.37	0.38	0.03	0.86
Non-deriv MS/MS PE NeoGram	49	2.14	0.30	0.33	0.01	0.85

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

HEXANOYLCARNITINE (μmol C6/L whole blood)
- continued -

Method	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 561 - Nonenriched 0 μmol/L whole blood						
Derivatized-MS/MS Non-Kit	610	0.06	0.03	0.06	0.06	0.90
Non-derivatized MS/MS Non-Kit	20	0.02	0.02	0.02	-0.01	0.95
Deriv-MS/MS PE NeoGram	166	0.06	0.03	0.04	0.07	0.86
Non-deriv MS/MS PE NeoGram	29	0.03	0.02	0.03	0.06	0.75
Lot 562 - Enriched 0.5 μmol/L whole blood						
Derivatized-MS/MS Non-Kit	600	0.50	0.08	0.14	0.06	0.90
Non-derivatized MS/MS Non-Kit	20	0.46	0.07	0.12	-0.01	0.95
Deriv-MS/MS PE NeoGram	162	0.50	0.10	0.11	0.07	0.86
Non-deriv MS/MS PE NeoGram	29	0.47	0.09	0.17	0.06	0.75
Lot 563 - Enriched 1 μmol/L whole blood						
Derivatized-MS/MS Non-Kit	605	0.98	0.15	0.26	0.06	0.90
Non-derivatized MS/MS Non-Kit	20	0.90	0.15	0.23	-0.01	0.95
Deriv-MS/MS PE NeoGram	166	0.95	0.15	0.18	0.07	0.86
Non-deriv MS/MS PE NeoGram	29	0.82	0.08	0.14	0.06	0.75
Lot 564 - Enriched 2.5 μmol/L whole blood						
Derivatized-MS/MS Non-Kit	607	2.31	0.31	0.60	0.06	0.90
Non-derivatized MS/MS Non-Kit	20	2.38	0.28	0.32	-0.01	0.95
Deriv-MS/MS PE NeoGram	163	2.22	0.34	0.39	0.07	0.86
Non-deriv MS/MS PE NeoGram	29	1.93	0.27	0.30	0.06	0.75

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

TABLE 7q. 2005 Quality Control Data
Summaries of Statistical Analyses

OCTANOYLCARNITINE (μmol C8/L whole blood)

Method	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 461 - Nonenriched 0 μmol/L whole blood						
Derivatized-MS/MS Non-Kit	1092	0.09	0.05	0.06	0.06	1.10
Non-derivatized MS/MS Non-Kit	133	0.06	0.03	0.04	0.03	1.09
Deriv-MS/MS PE NeoGram	250	0.07	0.03	0.04	0.05	0.97
Non-deriv MS/MS PE NeoGram	58	0.06	0.02	0.03	0.05	0.98
Lot 462 - Enriched 0.5 μmol/L whole blood						
Derivatized-MS/MS Non-Kit	1067	0.57	0.10	0.12	0.06	1.10
Non-derivatized MS/MS Non-Kit	132	0.53	0.08	0.10	0.03	1.09
Deriv-MS/MS PE NeoGram	250	0.50	0.10	0.10	0.05	0.97
Non-deriv MS/MS PE NeoGram	58	0.51	0.09	0.09	0.05	0.98
Lot 463 - Enriched 1 μmol/L whole blood						
Derivatized-MS/MS Non-Kit	1077	1.17	0.18	0.23	0.06	1.10
Non-derivatized MS/MS Non-Kit	132	1.14	0.14	0.15	0.03	1.09
Deriv-MS/MS PE NeoGram	254	1.03	0.19	0.21	0.05	0.97
Non-deriv MS/MS PE NeoGram	58	1.06	0.16	0.16	0.05	0.98
Lot 464 - Enriched 2.5 μmol/L whole blood						
Derivatized-MS/MS Non-Kit	1078	2.82	0.39	0.53	0.06	1.10
Non-derivatized MS/MS Non-Kit	133	2.76	0.36	0.39	0.03	1.09
Deriv-MS/MS PE NeoGram	252	2.47	0.35	0.43	0.05	0.97
Non-deriv MS/MS PE NeoGram	59	2.49	0.37	0.37	0.05	0.98

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

OCTANOYLCARNITINE (μmol C8/L whole blood)
- continued -

Method	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 561 - Nonenriched 0 μmol/L whole blood						
Derivatized-MS/MS Non-Kit	606	0.08	0.03	0.04	0.09	1.07
Non-derivatized MS/MS Non-Kit	55	0.08	0.04	0.07	0.07	1.07
Deriv-MS/MS PE NeoGram	182	0.08	0.03	0.04	0.08	0.91
Non-deriv MS/MS PE NeoGram	42	0.07	0.03	0.03	0.07	0.88
Lot 562 - Enriched 0.5 μmol/L whole blood						
Derivatized-MS/MS Non-Kit	600	0.62	0.10	0.15	0.09	1.07
Non-derivatized MS/MS Non-Kit	55	0.59	0.07	0.09	0.07	1.07
Deriv-MS/MS PE NeoGram	185	0.53	0.11	0.12	0.08	0.91
Non-deriv MS/MS PE NeoGram	39	0.54	0.10	0.14	0.07	0.88
Lot 563 - Enriched 1 μmol/L whole blood						
Derivatized-MS/MS Non-Kit	596	1.16	0.15	0.24	0.09	1.07
Non-derivatized MS/MS Non-Kit	56	1.13	0.12	0.16	0.07	1.07
Deriv-MS/MS PE NeoGram	182	0.99	0.18	0.22	0.08	0.91
Non-deriv MS/MS PE NeoGram	41	0.92	0.12	0.17	0.07	0.88
Lot 564 - Enriched 2.5 μmol/L whole blood						
Derivatized-MS/MS Non-Kit	590	2.75	0.34	0.57	0.09	1.07
Non-derivatized MS/MS Non-Kit	55	2.75	0.32	0.40	0.07	1.07
Deriv-MS/MS PE NeoGram	187	2.34	0.34	0.40	0.08	0.91
Non-deriv MS/MS PE NeoGram	40	2.29	0.29	0.41	0.07	0.88

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

TABLE 7r. 2005 Quality Control Data
Summaries of Statistical Analyses

DECANOYLCARNITINE (μmol C10/L whole blood)

Method	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 461 - Nonenriched 0 μmol/L whole blood						
Derivatized-MS/MS Non-Kit	1064	0.08	0.03	0.05	0.06	1.26
Non-derivatized MS/MS Non-Kit	77	0.06	0.03	0.03	0.02	1.23
Deriv-MS/MS PE NeoGram	267	0.07	0.04	0.04	0.05	0.88
Non-deriv MS/MS PE NeoGram	58	0.07	0.03	0.03	0.05	0.94
Lot 462 - Enriched 0.25 μmol/L whole blood						
Derivatized-MS/MS Non-Kit	1076	0.35	0.08	0.11	0.06	1.26
Non-derivatized MS/MS Non-Kit	79	0.31	0.07	0.08	0.02	1.23
Deriv-MS/MS PE NeoGram	267	0.26	0.06	0.07	0.05	0.88
Non-deriv MS/MS PE NeoGram	58	0.26	0.06	0.06	0.05	0.94
Lot 463 - Enriched 0.75 μmol/L whole blood						
Derivatized-MS/MS Non-Kit	1072	1.00	0.18	0.27	0.06	1.26
Non-derivatized MS/MS Non-Kit	76	0.91	0.16	0.19	0.02	1.23
Deriv-MS/MS PE NeoGram	268	0.71	0.14	0.17	0.05	0.88
Non-deriv MS/MS PE NeoGram	58	0.76	0.15	0.15	0.05	0.94
Lot 464 - Enriched 1.5 μmol/L whole blood						
Derivatized-MS/MS Non-Kit	1066	1.95	0.33	0.50	0.06	1.26
Non-derivatized MS/MS Non-Kit	79	1.89	0.31	0.39	0.02	1.23
Deriv-MS/MS PE NeoGram	269	1.39	0.23	0.29	0.05	0.88
Non-deriv MS/MS PE NeoGram	59	1.46	0.31	0.32	0.05	0.94

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

DECANOYLCARNITINE (μmol C10/L whole blood)
- continued -

Method	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 561 - Nonenriched 0 μmol/L whole blood						
Derivatized-MS/MS Non-Kit	567	0.09	0.03	0.04	0.08	1.24
Non-derivatized MS/MS Non-Kit	29	0.07	0.02	0.02	0.07	1.09
Deriv-MS/MS PE NeoGram	189	0.08	0.04	0.05	0.09	0.85
Non-deriv MS/MS PE NeoGram	42	0.09	0.07	0.08	0.10	0.86
Lot 562 - Enriched 0.25 μmol/L whole blood						
Derivatized-MS/MS Non-Kit	566	0.39	0.07	0.11	0.08	1.24
Non-derivatized MS/MS Non-Kit	29	0.36	0.04	0.06	0.07	1.09
Deriv-MS/MS PE NeoGram	174	0.30	0.07	0.08	0.09	0.85
Non-deriv MS/MS PE NeoGram	42	0.32	0.08	0.12	0.10	0.86
Lot 563 - Enriched 0.75 μmol/L whole blood						
Derivatized-MS/MS Non-Kit	561	1.00	0.15	0.26	0.08	1.24
Non-derivatized MS/MS Non-Kit	30	0.86	0.09	0.20	0.07	1.09
Deriv-MS/MS PE NeoGram	184	0.73	0.13	0.16	0.09	0.85
Non-deriv MS/MS PE NeoGram	42	0.75	0.18	0.22	0.10	0.86
Lot 564 - Enriched 1.5 μmol/L whole blood						
Derivatized-MS/MS Non-Kit	582	1.95	0.30	0.57	0.08	1.24
Non-derivatized MS/MS Non-Kit	29	1.71	0.19	0.29	0.07	1.09
Deriv-MS/MS PE NeoGram	181	1.36	0.20	0.27	0.09	0.85
Non-deriv MS/MS PE NeoGram	42	1.39	0.26	0.29	0.10	0.86

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

TABLE 7s. 2005 Quality Control Data
Summaries of Statistical Analyses

MYRISTOYLCARNITINE (μmol C14/L whole blood)

Method	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 461 - Nonenriched 0 μmol/L whole blood						
Derivatized-MS/MS Non-Kit	1047	0.18	0.07	0.09	0.14	1.00
Non-derivatized MS/MS Non-Kit	55	0.13	0.06	0.10	0.08	1.03
Deriv-MS/MS PE NeoGram	216	0.14	0.04	0.05	0.13	0.85
Non-deriv MS/MS PE NeoGram	59	0.12	0.04	0.05	0.09	0.75
Lot 462 - Enriched 0.5 μmol/L whole blood						
Derivatized-MS/MS Non-Kit	1027	0.58	0.10	0.14	0.14	1.00
Non-derivatized MS/MS Non-Kit	57	0.56	0.11	0.17	0.08	1.03
Deriv-MS/MS PE NeoGram	219	0.54	0.10	0.11	0.13	0.85
Non-deriv MS/MS PE NeoGram	58	0.44	0.08	0.14	0.09	0.75
Lot 463 - Enriched 1.5 μmol/L whole blood						
Derivatized-MS/MS Non-Kit	1051	1.65	0.51	0.62	0.14	1.00
Non-derivatized MS/MS Non-Kit	56	1.59	0.37	0.40	0.08	1.03
Deriv-MS/MS PE NeoGram	221	1.42	0.22	0.27	0.13	0.85
Non-deriv MS/MS PE NeoGram	59	1.21	0.17	0.33	0.09	0.75
Lot 464 - Enriched 3 μmol/L whole blood						
Derivatized-MS/MS Non-Kit	1034	3.15	0.46	0.74	0.14	1.00
Non-derivatized MS/MS Non-Kit	58	3.20	0.46	0.56	0.08	1.03
Deriv-MS/MS PE NeoGram	220	2.69	0.38	0.51	0.13	0.85
Non-deriv MS/MS PE NeoGram	59	2.36	0.37	0.73	0.09	0.75

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

MYRISTOYLCARNITINE (μmol C14/L whole blood)
- continued -

Method	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 561 - Nonenriched 0 μmol/L whole blood						
Derivatized-MS/MS Non-Kit	592	0.13	0.05	0.08	0.10	1.00
Non-derivatized MS/MS Non-Kit	20	0.08	0.03	0.03	0.02	0.98
Deriv-MS/MS PE NeoGram	166	0.12	0.05	0.06	0.08	0.91
Non-deriv MS/MS PE NeoGram	40	0.08	0.04	0.05	0.04	0.66
Lot 562 - Enriched 0.5 μmol/L whole blood						
Derivatized-MS/MS Non-Kit	608	0.55	0.11	0.17	0.10	1.00
Non-derivatized MS/MS Non-Kit	20	0.48	0.07	0.07	0.02	0.98
Deriv-MS/MS PE NeoGram	165	0.47	0.08	0.10	0.08	0.91
Non-deriv MS/MS PE NeoGram	39	0.33	0.07	0.12	0.04	0.66
Lot 563 - Enriched 1.5 μmol/L whole blood						
Derivatized-MS/MS Non-Kit	588	1.61	0.23	0.38	0.10	1.00
Non-derivatized MS/MS Non-Kit	20	1.45	0.19	0.29	0.02	0.98
Deriv-MS/MS PE NeoGram	174	1.47	0.24	0.31	0.08	0.91
Non-deriv MS/MS PE NeoGram	38	1.02	0.19	0.37	0.04	0.66
Lot 564 - Enriched 3 μmol/L whole blood						
Derivatized-MS/MS Non-Kit	596	3.09	0.43	0.77	0.10	1.00
Non-derivatized MS/MS Non-Kit	19	3.01	0.23	0.23	0.02	0.98
Deriv-MS/MS PE NeoGram	157	2.80	0.36	0.43	0.08	0.91
Non-deriv MS/MS PE NeoGram	40	2.02	0.28	0.65	0.04	0.66

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

TABLE 7t. 2005 Quality Control Data
Summaries of Statistical Analyses

PALMITOYLCARNITINE (μmol C16/L whole blood)

Method	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 461 - Nonenriched 0 μmol/L whole blood						
Derivatized-MS/MS Non-Kit	1083	1.50	0.21	0.35	1.17	0.98
Non-derivatized MS/MS Non-Kit	77	1.39	0.27	0.32	1.09	0.99
Deriv-MS/MS PE NeoGram	245	1.29	0.20	0.24	1.04	0.90
Non-deriv MS/MS PE NeoGram	49	1.56	0.24	0.24	1.20	1.05
Lot 462 - Enriched 4 μmol/L whole blood						
Derivatized-MS/MS Non-Kit	1061	4.66	0.58	0.93	1.17	0.98
Non-derivatized MS/MS Non-Kit	78	4.66	0.81	1.06	1.09	0.99
Deriv-MS/MS PE NeoGram	246	4.30	0.54	0.64	1.04	0.90
Non-deriv MS/MS PE NeoGram	50	4.99	0.78	0.80	1.20	1.05
Lot 463 - Enriched 8 μmol/L whole blood						
Derivatized-MS/MS Non-Kit	1073	8.89	1.11	1.88	1.17	0.98
Non-derivatized MS/MS Non-Kit	79	8.98	1.51	2.00	1.09	0.99
Deriv-MS/MS PE NeoGram	245	8.07	1.12	1.44	1.04	0.90
Non-deriv MS/MS PE NeoGram	49	9.39	0.98	1.89	1.20	1.05
Lot 464 - Enriched 12 μmol/L whole blood						
Derivatized-MS/MS Non-Kit	1095	13.17	1.60	2.71	1.17	0.98
Non-derivatized MS/MS Non-Kit	79	13.21	1.81	3.11	1.09	0.99
Deriv-MS/MS PE NeoGram	246	11.97	1.51	1.89	1.04	0.90
Non-deriv MS/MS PE NeoGram	49	14.13	1.32	1.72	1.20	1.05

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

PALMITOYLCARNITINE (μmol C16/L whole blood)
- continued -

Method	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 561 - Nonenriched 0 μmol/L whole blood						
Derivatized-MS/MS Non-Kit	616	1.01	0.18	0.31	1.03	0.89
Non-derivatized MS/MS Non-Kit	29	0.97	0.17	0.21	0.88	0.88
Deriv-MS/MS PE NeoGram	176	0.98	0.17	0.20	0.88	0.88
Non-deriv MS/MS PE NeoGram	29	0.92	0.11	0.15	0.85	0.88
Lot 562 - Enriched 4 μmol/L whole blood						
Derivatized-MS/MS Non-Kit	618	4.56	0.53	0.93	1.03	0.89
Non-derivatized MS/MS Non-Kit	28	4.34	0.25	0.40	0.88	0.88
Deriv-MS/MS PE NeoGram	177	4.29	0.55	0.66	0.88	0.88
Non-deriv MS/MS PE NeoGram	30	4.31	0.54	0.65	0.85	0.88
Lot 563 - Enriched 8 μmol/L whole blood						
Derivatized-MS/MS Non-Kit	621	8.20	0.95	1.68	1.03	0.89
Non-derivatized MS/MS Non-Kit	28	7.77	0.70	0.76	0.88	0.88
Deriv-MS/MS PE NeoGram	178	7.81	0.85	1.21	0.88	0.88
Non-deriv MS/MS PE NeoGram	30	7.77	0.70	0.70	0.85	0.88
Lot 564 - Enriched 12 μmol/L whole blood						
Derivatized-MS/MS Non-Kit	601	11.60	1.35	2.33	1.03	0.89
Non-derivatized MS/MS Non-Kit	29	11.56	1.13	1.30	0.88	0.88
Deriv-MS/MS PE NeoGram	175	11.50	1.25	1.55	0.88	0.88
Non-deriv MS/MS PE NeoGram	30	11.48	1.27	1.49	0.85	0.88

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

NOTES

This ***NEWBORN SCREENING QUALITY ASSURANCE PROGRAM*** report is an internal publication distributed to program participants and selected program colleagues. The laboratory quality assurance program is a project cosponsored by the **Centers for Disease Control and Prevention (CDC) and the Association of Public Health Laboratories.**

CENTERS FOR DISEASE CONTROL AND PREVENTION (CDC)
ATLANTA, GA 30341

Director
Julie Louise Gerberding, M.D., M.P.H.
Director
National Center for Environmental Health
Howard Frumkin, M.D., Dr.P.H., M.P.H.
Director
Division of Laboratory Sciences
Eric J. Sampson, Ph.D.
Chief
Newborn Screening Branch
W. Harry Hannon, Ph.D.

Contributors:
Barbara W. Adam
Carol Bell
Paul Dantonio
Marie C. Earley, Ph.D.
F. Hugh Gardner
Sherri Hall
L. Omar Henderson, Ph.D.
Lisa Kalman, Ph.D.
Lixia Li, Ph.D.
Timothy Lim, Ph.D.
Elizabeth McCown
Joanne Mei, Ph.D.
Nancy Meredith
Hetal Patel
Jarad Schiffer
Anand Swamy, Ph.D.
Robert Vogt, Ph.D.
Yingtao Zhou

Production:
Sarah Brown
Felicia Manning
Connie Singleton

ASSOCIATION OF PUBLIC HEALTH LABORATORIES
WASHINGTON, DC 20036-3320

President
Katherine Kelley, Dr.P.H.
Chairman, Newborn Screening and Genetics in Public Health Committee
William Becker, D.O., M.P.H.
Chairman, Newborn Screening Quality Assurance Subcommittee
John Sherwin, Ph.D.

INQUIRIES TO:

Carol Bell, Editor ● Centers for Disease Control and Prevention (CDC)
Newborn Screening Quality Assurance Program ● Mailstop F-43
4770 Buford Highway, N.E. ● Atlanta, GA 30341-3724
Phone (770) 488-4582 ● FAX (770) 488-4255 ● E-mail: CBell@cdc.gov